EXHIBIT A.1

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

In Re: Bard IVC Filters Products Liability Litigation	MD-15-02641-PHX-DGC
	Phoenix, Arizona
	March 29, 2018
Sherr-Una Booker, an individual,	
Plaintiff,	
v.	CV-16-00474-PHX-DGC
C.R. Bard, Inc., a New Jersey corporation; and Bard Peripheral Vascular, Inc., an Arizona corporation,	
Defendants.	

BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

REPORTER'S TRANSCRIPT OF PROCEEDINGS

TRIAL DAY 11

(Pages 2439 - 2570)

Official Court Reporter:
Patricia Lyons, RMR, CRR
Sandra Day O'Connor U.S. Courthouse, Ste. 312
401 West Washington Street, SPC 41
Phoenix, Arizona 85003-2150
(602) 322-7257

Proceedings Reported by Stenographic Court Reporter
Transcript Prepared with Computer-Aided Transcription

an issue on posttrial appeal.

So that's the reason I thought it ought to be included. But now I'm interested in your comments.

MR. STOLLER: Well, I think it emphasizes, a way, -- in a way it does not, other defenses and issues, that it tells them go back and look again, did you really do this, did you not do this, and emphasizes a defense to the claims in a way that's not true for other things or other elements of the claims.

For example, we don't ask them that question as to assumption of the risk, which is an affirmative defense in -- and I'm not advocating that you add it. But it does -- it highlights things in way for them in a way that we all know, well, at least from our jury observation after the fact, is that they take these instructions seriously, they take the verdict form seriously, they read them and assume that the things they're asked to do have particular meaning.

And our concern, my concern, is that these questions put particular emphasis on a defense that is obviously designed to defeat liability and damages in this case.

THE COURT: Okay. I understand that. Thank you.

Defense counsel, your thoughts.

MS. HELM: Your Honor, we have no -- we're comfortable with the verdict form. We don't have anything.

THE COURT: All right.

C E R T I F I C A T E

I, PATRICIA LYONS, do hereby certify that I am duly appointed and qualified to act as Official Court Reporter for the United States District Court for the District of Arizona.

I FURTHER CERTIFY that the foregoing pages constitute a full, true, and accurate transcript of all of that portion of the proceedings contained herein, had in the above-entitled cause on the date specified therein, and that said transcript was prepared under my direction and control, and to the best of my ability.

DATED at Phoenix, Arizona, this 30th day of March, 2018.

s/ Patricia Lyons, RMR, CRR
Official Court Reporter

EXHIBIT A.2
(Filed Under Seal)

EXHIBIT A.3

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

In Re: Bard IVC Filters Products Liability Litigation	MD-15-02641-PHX-DGC
	Phoenix, Arizona
	March 15, 2018
Sherr-Una Booker, an individual,	
Plaintiff,	
v.	CV-16-00474-PHX-DGC
C.R. Bard, Inc., a New Jersey corporation; and Bard Peripheral Vascular, Inc., an Arizona corporation,	
Defendant.	

BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

REPORTER'S TRANSCRIPT OF PROCEEDINGS

TRIAL DAY 2 A.M. SESSION

(Pages 216 - 336)

Official Court Reporter:
Patricia Lyons, RMR, CRR
Sandra Day O'Connor U.S. Courthouse, Ste. 312
401 West Washington Street, SPC 41
Phoenix, Arizona 85003-2150
(602) 322-7257

Proceedings Reported by Stenographic Court Reporter
Transcript Prepared with Computer-Aided Transcription

09:13:22 A Correct.
Q And the G2 filter was released to the market in 2005; correct?
A I don't have an exact recollection, but, yes, roughly
09:13:36 around that time.
Q All right. And if we go to Bates 867 --
MR. O'CONNOR: Will you go there, Greg.
And, Greg, can you call out the Weaknesses section of this SWOT document, increased revenue and capture more market
09:13:56 share.
BY MR. O'CONNOR:
Q And, sir, do you see where this document that's been produced by Bard states "Weaknesses." Under the term "Weaknesses," "Lack of full understanding dynamics caval
09:14:09 anatomy impacting testing methods."
Did I read that correctly?
A Yes.
Q The document goes on to state that Bard: We have a historical reactive/evolution design mindset.
09:14:31 Did I read that correctly?
A Yes, that's correct.
Q It goes on to say: Product complications-forcing focus on reactive designing.
Did I read that correctly?
09:14:45 A Yes.

C E R T I F I C A T E

I, PATRICIA LYONS, do hereby certify that I am duly appointed and qualified to act as Official Court Reporter for the United States District Court for the District of Arizona.

I FURTHER CERTIFY that the foregoing pages constitute a full, true, and accurate transcript of all of that portion of the proceedings contained herein, had in the above-entitled cause on the date specified therein, and that said transcript was prepared under my direction and control, and to the best of my ability.

DATED at Phoenix, Arizona, this 16th day of March, 2018.

s/ Patricia Lyons, RMR, CRR
Official Court Reporter

EXHIBIT A.4

March 28, 2018 P.M.

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

In re: Bard IVC Filters, Products Liability Litigation	MD-15-02641-PHX-DGC
Sherr-Una Booker, an individual, Plaintiff, v. **C.R. Bard, Inc., a New Jersey corporation; and Bard Peripheral Vascular, Inc., an Arizona corporation,** Defendants.	Phoenix, Arizona March 28, 2018 12:50 p.m. CV-16-00474-PHX-DGC

BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

REPORTER'S TRANSCRIPT OF PROCEEDINGS

JURY TRIAL - DAY 10 P.M.

(Pages 2297 through 2438)

Official Court Reporter:
Elaine Cropper, RDR, CRR, CCP
Sandra Day O'Connor U.S. Courthouse
401 West Washington Street
Suite 312, SPC 35
Phoenix, Arizona 85003-2150
(602) 322-7245

Proceedings Reported by Stenographic Court Reporter
Transcript Prepared by Computer-Aided Transcription

to the warning. 12:59:27

THE COURT: Which one is it?

MS. LOURIE: It's the failure to warn. It was that sentence about the warning being inadequate if it does not provide a complete disclosure of both the existence of the risk 12:59:38 and the extent of the danger and severity of any potential injury involved.

THE COURT: Right. Okay. That is on the record.

How about from the defense side?

MR. NORTH: Your Honor, the only things we would like 12:59:48 to preserve for the record was our request number four, which the Court just mentioned, about the failure to read the warning and our request number ten about punitive damages and dissimilar conduct. We believe both of those should have been given. 01:00:02

THE COURT: Dissimilar conduct has been added. It's at the end of instruction A at the end of the materials and I added that, by the way, because that's a pattern Georgia jury instruction in a punitive damages case. So the last paragraph in instruction A, which is only going to be given if the jury 01:00:36 decides to award damages, includes that idea.

MR. NORTH: Then we're down to just number four, Your Honor.

THE COURT: Okay.

MR. STOLLER: I'll amend then what I said before, 01:00:48

C E R T I F I C A T E

I, ELAINE M. CROPPER, do hereby certify that I am duly appointed and qualified to act as Official Court Reporter for the United States District Court for the District of Arizona.

I FURTHER CERTIFY that the foregoing pages constitute a full, true, and accurate transcript of all of that portion of the proceedings contained herein, had in the above-entitled cause on the date specified therein, and that said transcript was prepared under my direction and control, and to the best of my ability.

DATED at Phoenix, Arizona, this 29th day of March, 2018.

s/Elaine M. Cropper

Elaine M. Cropper, RDR, CRR, CCP

EXHIBIT A.5

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

In Re: Bard IVC Filters Products Liability Litigation	MD-15-02641-PHX-DGC
	Phoenix, Arizona
	March 30, 2018
Sherr-Una Booker, an individual,	
Plaintiff,	
v.	CV-16-00474-PHX-DGC
C.R. Bard, Inc., a New Jersey corporation; and Bard Peripheral Vascular, Inc., an Arizona corporation,	
Defendants.	

BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

REPORTER'S TRANSCRIPT OF PROCEEDINGS

TRIAL DAY 12 (VERDICT)

(Pages 2571 - 2620)

Official Court Reporter:
Patricia Lyons, RMR, CRR
Sandra Day O'Connor U.S. Courthouse, Ste. 312
401 West Washington Street, SPC 41
Phoenix, Arizona 85003-2150
(602) 322-7257

Proceedings Reported by Stenographic Court Reporter
Transcript Prepared with Computer-Aided Transcription

10:01:31

P R O C E E D I N G S

(Proceedings resumed in open court outside the presence of the jury.)

09:30:13

THE COURT: Thank you. Please be seated.

Morning, everybody.

EVERYBODY: Morning, Your Honor.

THE COURT: We've been informed that the jury has reached a verdict. We will bring them in at this time.

09:30:30

(The jury entered the courtroom.)

THE COURT: Thank you. Please be seated.

All right. Which one of you is the foreperson for the jury?

All right. Ma'am, has the jury reached a unanimous

09:32:18

verdict?

JURY FOREPERSON: We have, Your Honor.

THE COURT: Would you hand the folder to, Nancy, please.

All right. I'm going to have Traci read the verdict.

09:33:29

THE COURTROOM DEPUTY: Omitting the formal caption: We, the Jury, duly empaneled and sworn in the above entitled action, upon our oaths, find as follows:

Liability. Number 1. Strict Product Liability Design Defect Claim.

09:33:46

Do you find by a preponderance of the evidence that

09:33:49 Bard is liable to Ms. Booker on the strict product liability design defect claim?

No.

Number 2. Strict Product Liability Failure to Warn

09:34:03 Claim.

Do you find by a preponderance of the evidence that Bard is liable to Ms. Booker on the strict product liability failure to warn claim?

No.

09:34:18 Number 3. Do you find by a preponderance of the evidence that Bard is liable to Ms. Booker on the negligent design claim?

No.

Number 4. Negligent Failure to Warn Claim.

09:34:35 Do you find by a preponderance of the evidence that Bard is liable to Ms. Booker on the negligent failure to warn claim?

Yes.

B. Compensatory Damages.

09:34:52 If you found Bard liable on any of the claims set forth above, what amount of damages do you find will reasonably compensate Ms. Booker for her injuries?

2 million.

C. Apportionment of Fault.

09:35:07 Number 1. Do you find by a preponderance of the

09:35:10 evidence that negligence on the part of Dr. Sarwat Amer caused or contributed to Ms. Booker's injuries?

Yes.

If you answered yes, please provide the relative
09:35:27 degree of fault, if any, that you assign to Bard and Dr. Amer. Your total must equal 100 percent.

Bard 80 percent, Dr. Amer 20 percent.

Punitive Damages.

Do you find by clear and convincing evidence that
09:35:46 punitive damages should be awarded against Bard?

Yes.

Answer to Question Number 2. If you answered yes to any question identified in part A above, did you reduce the damages awarded in part B based on the fact that either of the
09:36:08 following was a superseding cause:

Dr. Brandon Kang? No.

Other radiologists? No.

Signed by foreperson Juror Number 3, March 30th, 2018.

09:36:21 THE COURT: All right. Traci, would you please poll the jury.

THE COURTROOM DEPUTY: Juror Number 1, are these your verdicts?

JUROR: Yes.

09:36:27 THE COURTROOM DEPUTY: Juror Number 2, are these your

verdicts?

JUROR: Yes.

THE COURTROOM DEPUTY: Juror Number 3, are these your verdicts?

JUROR: Yes.

THE COURTROOM DEPUTY: Juror Number 4, are these your verdicts?

JUROR: Yes.

THE COURTROOM DEPUTY: Juror Number 5, are these your verdicts?

JUROR: Yes.

THE COURTROOM DEPUTY: Juror Number 6, are these your verdicts?

JUROR: Yes.

THE COURTROOM DEPUTY: Juror Number 7, are these your verdicts?

JUROR: Yes.

THE COURTROOM DEPUTY: Juror Number 8, are these your verdicts?

JUROR: Yes.

THE COURTROOM DEPUTY: Juror Number 9, are these your verdicts?

JUROR: Yes.

THE COURT: All right. The polling has shown that the verdict is unanimous.

09:36:55 Ladies and gentlemen, as you know, because you've concluded that punitive damages should be awarded, we need to give you some additional evidence and additional instructions.

Let me talk to the counsel at sidebar for a minute and we'll figure out how most quickly and efficiently to get that done.

(Bench conference as follows:)

THE COURT: All right. Plaintiff's counsel, you said yesterday you had 18 minutes of evidence you wanted --

09:37:37 MR. STOLLER: Actually less than that, but I think the total run time is about 16 minutes.

THE COURT: Okay. And I allotted 35 minutes for the punitive damages case.

Do you have evidence that you all are going --

09:37:47 MR. NORTH: We have counter-designations in the same --

THE COURT: It's in the same thing? So the 16 minutes includes both?

MR. STOLLER: Sorry?

09:37:57 THE COURT: Does the 16 minutes include designations and counter-designations?

MR. STOLLER: I don't have it -- it's less than 20 minutes.

THE COURT: Okay. And that's the only evidence to be

09:38:05 presented?

10:07:46 The intent of Bard in committing the wrong;

The profitability of Bard's wrongdoing;

The amount of compensatory damages you have previously awarded;

10:08:00 The financial circumstances, that is, the financial condition or net worth of Bard.

In making an award of punitive damages, you should consider the degree of reprehensibility of Bard's wrongdoing. You should consider all of the evidence, both aggravating and

10:08:17 mitigating, to decide how much punishment, penalty, or deterrence Bard's conduct deserves in the form of punitive damages.

In assessing reprehensibility, you may consider whether the harm caused was physical, as opposed to economic;

10:08:36 the conduct showed an indifference to or reckless disregard of the health or safety of others; and the conduct involved repeated actions or was an isolated incident.

You may have heard evidence of other conduct and procedures of Bard. For the purposes of punitive damages, you

10:08:55 may not consider evidence of any conduct of Bard that is dissimilar to that which resulted in Ms. Booker's injury, unless such dissimilar conduct was related to the specific harm suffered by Ms. Booker in this case.

All right. Plaintiff's counsel, your argument.

10:09:16 MS. HELM: Excuse me, Your Honor, before we begin

10:09:18 argument, may we approach at sidebar?

THE COURT: Sure.

If you want to stand up, ladies and gentlemen, feel free.

10:09:36 (Bench conference as follows:)

MS. HELM: Your Honor, in light of the evidence that was just presented on the punitive damages claim, I believe that we would request a limiting instruction before argument occurs, limiting the jury that they cannot consider evidence 10:09:55 of out of Georgia conduct to punish the defendant under *Gore* and *State Farm versus Campbell*.

There are a number of cases that have addressed this issue, and we believe that you should instruct them that they should -- I mean, I can read through the cases, but we believe 10:10:19 you should instruct them that they cannot consider conduct that occurred outside of the state of Georgia in determining their punitive damages award.

THE COURT: Why wasn't this raised during our discussions of jury instructions?

10:10:32 MS. HELM: Your Honor, at that time we didn't have the evidence. We didn't know that the evidence was going to be --

THE COURT: But we knew the conduct was from Georgia. There's nothing in the deposition we just heard that said 10:10:43 anything about conduct in Georgia.

10:10:47 MS. HELM: Yes, Your Honor. And I raised that objection prior to the deposition being raised. But we believe that the lawyers -- to protect the record, that you should give a limiting instruction that they can't punish for
10:10:58 activities outside of the state of Georgia.

THE COURT: Well, the problem I have, Ms. Helm, is that I haven't read any of the cases you've cited. We're in the midst of presentation on punitive damages. The fact that the conduct in this case was in Georgia has been apparent from
10:11:13 the start of the trial, and so it seems very late in the game to be asking for a jury instruction that depends on cases I don't have time to read.

MS. HELM: Your Honor, I appreciate that. The actual pattern charge in Georgia contains this information with
10:11:29 conduct in it.

THE COURT: Well, then why wasn't it requested?

MS. HELM: It was Your Honor. The language -- I apologize. It's not part -- it's not the words in the pattern charge, but there's a long discussion of it in the pattern
10:11:41 charge, and we included that.

THE COURT: But you never mentioned that when we were talking about the punitive damages instruction at any of the three discussions we had.

MS. HELM: That's correct, Your Honor. But I believe
10:11:54 under *Gore* and under *State Farm*, and frankly to protect our

record, we believe that a limiting instruction is appropriate, and so we're asking for it.

THE COURT: Okay.

MR. STOLLER: Your Honor, I would only reiterate what you said, that this -- what we were going to present has been known since before the trial started. This deposition, as you know, was specifically authorized by the Court for us to take this deposition before the trial date. They've known what the testimony's going to be. This issue has not come up before now. We've had, as you know, extensive discussions on jury instructions.

I've not had an opportunity to review any of these cases either. But to the extent that the Georgia instruction talks about the net worth of a company, talks about the financial condition of a company is factors to be considered, which, in the evidence we put on, I can't imagine it's correct that we'd have to segregate out the net worth of the company as it's attributable to Georgia. In fact, I don't know how you do that.

THE COURT: I don't think that's what she's asking.

MR. STOLLER: I understand that. My point is on certainly the financial information we have presented, it's not segregable. I think it's consistent with the Georgia instruction.

THE COURT: All right. Well, I am not going to give

10:13:01 the instruction because it's being raised untimely. We had ample opportunity to settle the punitive damages instruction; in fact, we did, and I added the last paragraph at the defendants' request. And it would be unfair to add something 10:13:16 now on the basis of cases I haven't read and the plaintiff's counsel haven't read, so I'm not going to add that. But it's on the record.

MS. HELM: Thank you, Your Honor.

(Bench conference concludes.)

10:13:30 THE COURT: Thank you, ladies and gentlemen.

We will now have argument from plaintiff's counsel.

MR. O'CONNOR: Your Honor, may I move the podium and the board up?

THE COURT: Yeah.

10:14:49 MR. O'CONNOR: Good morning.

We need to talk about Bard's conscious indifference. The indifference that Bard showed to the world. To this country. To the medical community. To the patients who received the products. And the way they went about it.

10:15:22 And when we talk about conscious indifference and we talk about reprehensibility, I think that it's important that we go back and look at the workings of Bard. The suits, the money people versus the science people.

Greg, let's put up Exhibit 4327.

10:15:50 First page, please.

must not harm us as a community. They must not deprive companies and individuals and inventors of incentives to try to improve technology to treat us as patients and as human beings.

10:45:30 So, ladies and gentlemen, if you must, I ask that you enter a punitive award that is reasonable. That's fair to both parties. And that considers the impact that anything you do may have because, once again, I assure you, these men and women have and will hear your message.

10:45:52 Thank you.

THE COURT: All right. Thank you, Mr. North.

Mr. O'Connor, you have three minutes remaining.

MR. LOPEZ: We have to approach.

MR. O'CONNOR: May we approach?

10:46:01 THE COURT: Does it concern what's going to be argued?

MR. LOPEZ: No. It involves a motion in limine we feel has been violated.

THE COURT: Well, okay. Come on up.

10:46:11 Stand up, ladies and gentlemen.

(Bench conference as follows:)

MR. LOPEZ: In Motion in Limine Number 8, plaintiff asserts that --

THE COURT: Don't read me anything. What's the

10:46:34 point?

10:46:34 MR. LOPEZ: Your Honor, he violated Motion in Limine Number 8, which was granted. If he was going to want to put in evidence of the impact on the medical community, future medical device research or costs and availability of medical
10:46:49 care, his duty was if defendants believe such matters become relevant during trial, they may raise the issue with the Court outside the hearing of the jury. He just violated that motion in limine.

THE COURT: There was no objection made.

10:47:03 MR. LOPEZ: During his opening statement?

THE COURT: During his argument.

MR. LOPEZ: During his argument? We can still give an instruction to the jury.

THE COURT: Well, you can. But if you thought that
10:47:10 was violating a motion in limine, why didn't you object?

MR. LOPEZ: It was already out of his mouth.

THE COURT: What's your response?

MR. NORTH: My response is, Your Honor, I apologize. I should have gone and asked the Court's prior permission. I
10:47:23 believe that in the punitive phase it would be warranted under this instruction and the criteria to argue that, but I should have come and asked you that beforehand. I completely forgot about that.

THE COURT: Hold on just a minute.

10:48:05 What's the docket number?

10:48:08 MR. LOPEZ: 10075. 10075.

MS. REED ZAIC: Page 4.

THE COURT: Well, clearly that was a violation --

MR. NORTH: I understand.

10:49:26 THE COURT: -- of the motion in limine order.

MR. NORTH: I apologize.

THE COURT: The question is what do we do about it? And what I have to do to decide that is ask if he had raised it outside of the hearing of jury, would I allowed that

10:49:38 argument on the punitive damages phase of the case.

MR. LOPEZ: I don't think I agree with that. He should have done that with that.

THE COURT: Well, but if he had, we would have had the discussion we're about to have, which is, is it

10:49:47 permissible argument on punitive damages, and I would have made a decision. And if I had allowed it, then what he's done has not prejudiced you because I would have allowed it.

So what I need to hear from you, Mr. Lopez, is why you believe the argument is inappropriate at the punitive

10:50:05 damages stage.

MR. LOPEZ: Well, Your Honor, here's the thing. I think that had he raised this issue, as the motion would have requested him -- required him to do, your order, that he should have raised the issue with the Court outside of the

10:50:20 hearing of the jury.

10:50:22 THE COURT: Then we would have had this discussion.
MR. LOPEZ: We would have had this discussion.
THE COURT: So what's the point you would have made in that discussion?
10:50:27 MR. LOPEZ: The point I would have made is that the punitive damage instruction you just gave has nothing to do with the impact on the medical -- it doesn't even mention it in the instruction. There is nothing that segues the instruction you just gave on punitive damages to what happens
10:50:43 to the world, the medical community, the future medical device research, the costs and availability of medical care. It's not in the instruction. And he inserted that into your instruction, that they ought to consider these sorts of things.
10:50:58 Again, Your Honor, I can't help but go back to the fact that he knew he was going to do this. He has the motion in limine --
THE COURT: I want to talk about the merits of the point.
10:51:10 MR. LOPEZ: Okay.
THE COURT: You've established he violated the motion. I need to decide whether, had he raised it, it would have been appropriate for him to argue it.
MR. LOPEZ: Okay.
10:51:17 THE COURT: Do you have anything to else to say on

that?

MR. LOPEZ: Other than the fact that had he raised it, we might have had more time to do some research on it and come to you and say you're not supposed to do this in a punitive damage argument.

Now we're getting caught by surprise by something that was a violation of a motion in limine. And we're here not because of what we did, we're here because of what they did.

THE COURT: I understand that. But I need to make the decision about whether that is appropriate punitive damages argument. That's what I'm interested in.

MR. LOPEZ: Right.

THE COURT: And you've shared some thoughts on that. Do you have any others on that?

MR. LOPEZ: Just that it's outside of your instruction, Your Honor. It's prejudice to us that they now have to consider the impact on the rest of the world. It's just inappropriate.

THE COURT: All right.

Mr. North?

MR. NORTH: Your Honor, first of all, I want to, on the record, apologize. That was not intentional in the least. I'm sorry. At this moment, somewhat discombobulated by the verdict and the punitive award, I completely overlooked that,

10:52:09 and I do apologize.

Going on, the whole purpose of punitive damages is to deter. That is -- and that's what they're trying to do. That's the -- under Georgia law, the principles is deter from 10:52:23 future conduct.

Mr. O'Connor said "send a message" multiple times in his closing statement. I believe that it is important for the jury to understand the full consequences of the deterrence they are asking them to bring.

10:52:41 This is not a matter of -- at the liability phase where we tried to inject something like that for the finding. This is all in the context of their attempt to say that they need -- the jury needs to deter our conduct.

Also, mitigating circumstances are clearly an aspect 10:53:04 in the jury's assessment, and I think a mitigating circumstance is the ultimate impact of the jury's verdict.

And, Your Honor, I'm sorry. When I say the principles of deterring, that is the principal purpose of a punitive award, Your Honor has said that at the beginning of 10:53:28 this instruction where you talk about "and the purpose of punitive damages," which would have been referenced in the original jury instruction.

THE COURT: Okay.

I want to address another issue, Mr. Lopez. This is 10:54:53 what I'm wrestling with.

10:54:56 I don't think that the effect on the medical community is part of the instruction, and there's no evidence in front of the jury about that effect. However, Mr. O'Connor, in effect, asked the jury for a punitive verdict
10:55:11 of $1.7 billion when he threw out the 10 percent number.

You said 1 percent of 17 billion. Your math was wrong. That's $1.7 billion.

MR. O'CONNOR: Math.

THE COURT: Well, that is an extraordinary punitive
10:55:29 request.

It seems to me if you get up in front of this jury and argue for a billion-dollar-plus punitive amount, it isn't unreasonable for the other side to say consider the effect that will have on this company. Because that's an
10:55:47 extraordinary request.

And that was part of what Mr. North was arguing.

I'm interested in your response.

MR. LOPEZ: This company, this -- his argument was every company.

10:56:01 THE COURT: I understand.

MR. LOPEZ: The medical community at large, the effect it would have --

THE COURT: I understand.

MR. LOPEZ: Obviously we briefed that, and we have
10:56:07 some pretty good case law that would allow you to grant our

motion, and that he had a chance to brief it too.

And, you know, I understand -- no offense, they had that slide prepared in advance, and I think you would have required me, and I think we are all required, that if there's a motion in limine, Your Honor --

THE COURT: Don't come back to that, please. Let's -- I'm trying to make the decision of whether it's right for this to be argued --

MR. LOPEZ: He can certainly argue, and he did very effectively, the effect this would have on Bard. 1 percent of the sales, all these good people, and all the other things they do, the effects it would have on their company in doing the research and all these other products.

But then to put in front of the jury the effect this is going to have on the medical community, other medical device companies, and all things that he said outside of the effects on Bard is not relevant to the instruction you gave, and it is in violation of that motion in limine.

I understand what you're saying. He could argue all day long. He talked about the shareholders, the effects it's going to have on shareholders. Very effective argument, all those things.

But for him now to scare this jury, oh my God, you know, whatever we do to Bard is going to affect Gore, it's going to affect Johnson & Johnson, it's going to affect all

10:57:25 these other medical device companies, there's no evidence of it. It's just --

THE COURT: All right. I understand.

Had this been raised, I believe my ruling would have been that it is fair for the defendants to argue about the effect that the requested punitive damages would have on Bard and on Bard's work and on Bard's research, because I think that's all fair.

I believe I would have said you cannot argue, in effect, that there's going to be fewer services in the emergency room or in the hospital or less development of product by this verdict. I think that's where I would have drawn the line. Clearly, that was a part of the argument that was just made.

So I'm going to instruct the jury that in deciding punitive damages, they can consider the effect on Bard and its operations, but they cannot consider the effect that any punitive damages award would have on the larger medical community or development of medical products generally or the availability of medical products or services.

And that's the instruction I'll give to cure this error.

MR. LOPEZ: Thank you, Your Honor.

THE COURTROOM DEPUTY: The jury is asking for restroom a break.

10:59:10 THE COURT: Go ahead, let them go.

(The jury exited the courtroom.)

THE COURT: You've got three minutes, though. I gave you 20 when you got up, by the way. A little more than -- and

10:59:18 you used --

MR. O'CONNOR: Appreciate that.

THE COURT: You used, actually, 23 and a half.

MR. O'CONNOR: We already talked about I'm not good at math.

10:59:28 Thank you, Your Honor.

(Bench conference concludes.)

THE COURT: Counsel, would you approach for a minute, please.

(Bench conference as follows:)

11:02:20 THE COURT: As I was sketching out what I was going to say, I am a bit uncomfortable telling the jury what they can and cannot think about. I think the proper way to phrase the instruction is to say that they can consider defendants' arguments on Bard and its future operations and developments,

11:02:41 but they should disregard defendants' arguments on the effect on other companies, the medical community, et cetera.

So I'm not telling them you can't think about this. Jurors can think about whatever they choose. I'm just correcting what was argued.

11:02:58 Any comments on that?

11:26:46 JUROR: Yes.

THE COURTROOM DEPUTY: Juror Number 9, is this your verdict?

JUROR: Yes.

11:26:49 THE COURT: All right. The polling has shown this verdict to be unanimous.

Ladies and gentlemen, that finishes your work in this trial.

Thank you very much on behalf of the parties and all
11:26:59 of us here for the time you've spent on this case and the careful attention you've given to it.

We're going to excuse you at this time. You're also now no longer under the injunction that you can't talk about the case. If you want to talk to people, feel free.

11:27:13 I've reminded the parties that our local rules do not allow the parties to contact you without my permission, but if you want to talk to anybody else, you're welcome to do that.

So we'll excuse you. If you don't mind waiting for just a minute in the jury room, I'd like to come back and
11:27:30 thank you personally.

We will excuse the jury at this time.

(The jury exited the courtroom at 11:27.)

THE COURT: Counsel, I don't know if you've seen it, but I entered an order -- well, I don't know if it's been
11:27:55 entered; it should have been entered -- reflecting the things

C E R T I F I C A T E

I, PATRICIA LYONS, do hereby certify that I am duly appointed and qualified to act as Official Court Reporter for the United States District Court for the District of Arizona.

I FURTHER CERTIFY that the foregoing pages constitute a full, true, and accurate transcript of all of that portion of the proceedings contained herein, had in the above-entitled cause on the date specified therein, and that said transcript was prepared under my direction and control, and to the best of my ability.

DATED at Phoenix, Arizona, this 31st day of March, 2018.

s/ Patricia Lyons, RMR, CRR
Official Court Reporter

EXHIBIT A.6

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

In Re: Bard IVC Filters Products Liability Litigation	MD-15-02641-PHX-DGC
	Phoenix, Arizona
	March 22, 2018
Sherr-Una Booker, an individual,	
Plaintiff,	
v.	CV-16-00474-PHX-DGC
C.R. Bard, Inc., a New Jersey corporation; and Bard Peripheral Vascular, Inc., an Arizona corporation,	
Defendants.	Amended

BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

REPORTER'S AMENDED TRANSCRIPT OF PROCEEDINGS

TRIAL DAY 6 A.M. SESSION

(Pages 1079 - 1209)

Official Court Reporter:
Patricia Lyons, RMR, CRR
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401 West Washington Street, SPC 41
Phoenix, Arizona 85003-2150
(602) 322-7257

Proceedings Reported by Stenographic Court Reporter
Transcript Prepared with Computer-Aided Transcription

retrievable filter or a permanent filter; correct?

A It wasn't available, yes.

Q And that happened sometime near the end of 2005; correct?

A I believe so, yes.

MR. LOPEZ: Can we go down, there's a section there, Greg, on that page where it says "Data on File."

BY MR. LOPEZ:

Q And I should have pointed out, I don't want to go back to it, but those three things I just read had an asterisk next to it; right?

A Yes, they did.

Q And the asterisk is taking you to "Data on File"; right?

A That's correct.

Q Now, if a doctor wanted any of that data to support any of these claims, would Bard share that data with the doctor?

A No, we wouldn't.

Q Why wouldn't you share that with the doctor?

A Because the data is our -- it's based on our specifications, which are our property, if you will. All of them together kind of make up what makes the filter what it is, and so, no, we would not give somebody our specifications.

Q Okay. So if a sales -- if a doctor got the brochure and saw those three claims that Bard was making and thought, "Oh, data on file, I want to see what it is that supports these claims," Bard would not give that to the doctor. True?

09:22:31 A I'm sorry, I don't know that that ever happened. And, no, we would not give them our proprietary information.

Q Now, what if a doctor wanted Bard's G2 complication rates as it was being marketed? Would that be something that Bard

09:22:47 would give to the doctor?

A No, not necessarily.

Q What if Bard --

MR. LOPEZ: Greg, can you play 1618.

Let me tell you exactly.

09:23:09 Clip 3 from Mr. Carr's 4/17/13 deposition.

MR. WOODY: Play to the jury or --

MR. LOPEZ: Can I play this to the jury, Your Honor?

THE COURT: Any objection?

MR. NORTH: No, Your Honor.

09:23:41 THE COURT: Yes.

(Video clip played.)

"Question: Is there any reason why Bard wouldn't or couldn't provide this distraught physician with the complication rate associated with the G2 filter?"

09:23:57 "Answer: It's not something that we provide, no."

BY MR. LOPEZ:

Q Now, what if a doctor wanted G2's fracture resistance testing results to see whether or not the doctor was satisfied that this device, unlike the Recovery device, was more

09:24:14 fracture resistant? Would that be something that Bard would

09:24:18 give to the doctor?
A No, I don't think so.
MR. LOPEZ: Same deposition, Greg. Clip 4.
(Video clip played.)
09:24:32 "What about if a distraught physician wanted to know how the filter has been tested to see if it can resist fracture? Is he or she entitled to know that information?"
"Answer: No, it's confidential."
MR. LOPEZ: Can I have 994, please.
09:25:11 Traci, is this in evidence? I think it might be.
THE COURTROOM DEPUTY: 994?
MR. LOPEZ: 994.
THE COURTROOM DEPUTY: It is in.
MR. LOPEZ: This is in evidence, Your Honor. I'd
09:25:21 like to publish it to the jury.
THE COURT: You may.
BY MR. LOPEZ:
Q Sir, do you recognize this as the G2 IFU that we've been talking about?
09:25:36 THE WITNESS: Can you flip to the next page, please.
MR. LOPEZ: Don't put it large right now, leave it small.
This is the actual size that's --
THE WITNESS: The last page, please, can you flip
09:25:50 to -- yes.

C E R T I F I C A T E

I, PATRICIA LYONS, do hereby certify that I am duly appointed and qualified to act as Official Court Reporter for the United States District Court for the District of Arizona.

I FURTHER CERTIFY that the foregoing pages constitute a full, true, and accurate transcript of all of that portion of the proceedings contained herein, had in the above-entitled cause on the date specified therein, and that said transcript was prepared under my direction and control, and to the best of my ability.

DATED at Phoenix, Arizona, this 22nd day of March, 2018.

s/ Patricia Lyons, RMR, CRR
Official Court Reporter

EXHIBIT B.1

March 20, 2018 - P.M.

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

_____

In re: Bard IVC Filters, Products Liability Litigation	
	MD-15-02641-PHX-DGC
Sherr-Una Booker, an individual, Plaintiff, v.	Phoenix, Arizona March 20, 2018 12:59 p.m.
C.R. Bard, Inc., a New Jersey corporation; and Bard Peripheral Vascular, Inc., an Arizona corporation, Defendants.	CV-16-00474-PHX-DGC

BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

REPORTER'S TRANSCRIPT OF PROCEEDINGS

JURY TRIAL - DAY 4 P.M.

(Pages 780 through 899)

Official Court Reporter:
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exhibits that will be appearing in the video that I would like to read off and move into evidence. 04:07:17

Trial Exhibit 2244, which is D'Ayala Exhibit Number 2 at his deposition; Trial Exhibit 2057 is Exhibit 3 to his deposition; trial Exhibit 994, which is Exhibit Number 4 to his deposition; Trial Exhibit 2321, which is Exhibit Number 8 to his deposition; and Trial Exhibit 1001 which is Exhibit 13 to his deposition. 04:07:36

THE COURT: And are you moving those into evidence?

MS. REED ZAID: Yes, sir. 04:07:58

THE COURT: Any objection?

MS. HELM: No, Your Honor.

THE COURT: All right. Those exhibits will admitted. And you may play the deposition.

(Exhibit Numbers 2244, 2057, 994, 2321, 1001 were admitted into evidence.) 04:08:04

MS. REED ZAID: Thank you.

(Whereupon the deposition of Dr. D'Ayala was played.)

THE COURT: All right. Counsel. Let's stop the video there. 04:19:47

All right. We are at 4:20, ladies and gentlemen. We will plan to begin tomorrow morning at nine and we will excuse the jury at this time.

(Jury departs at 4:20.)

THE COURT: Please be seated. 04:20:22

C E R T I F I C A T E

I, ELAINE M. CROPPER, do hereby certify that I am duly appointed and qualified to act as Official Court Reporter for the United States District Court for the District of Arizona.

I FURTHER CERTIFY that the foregoing pages constitute a full, true, and accurate transcript of all of that portion of the proceedings contained herein, had in the above-entitled cause on the date specified therein, and that said transcript was prepared under my direction and control, and to the best of my ability.

DATED at Phoenix, Arizona, this 20th day of March, 2018.

s/Elaine M. Cropper

Elaine M. Cropper, RDR, CRR, CCP

EXHIBIT B.2

Designation Run Report

D'Ayala 03-21-17 Booker Depo Designation Final3.1

D, ayala 03-21-2017

Plaintiffs Designations 00:23:55

Defense Designations 00:16:37

Plaintiffs and defense Designations 00:00:50

Total Time 00:41:22

Page/Line	Source	ID

56:20 A. Yes.
56:21 Q. And you found in the conclusion, this
56:22 was actually presented in the Eastern Vascular
56:23 Society in DC in September of 2011, you found that
56:24 CPIVCF was associated with specific clinical
56:25 features, increased healthcare resource utilization
57:1 and higher mortality in patients undergoing
57:2 bariatric operations. Although selected patient
57:3 characteristics influenced surgeons to perform
57:4 CPIVCF, this study was unable to establish an
57:5 outcome benefit for CPIVCF.
57:6 That was a mouthful.
57:7 A. Yes.
57:8 Q. But can you tell us what that means?
57:9 A. What that means is that there appears
57:10 to be no benefit for morbidly obese patients
57:11 undergoing these procedures to undergo concurrent
57:12 placement of an IVC filter.
57:13 Q. So this filter in these -- in this
57:14 particular study was used prophylactically --
57:15 A. That is correct.
57:16 Q. -- to prevent PE post surgery from a
57:17 patient, correct?
57:18 A. Correct.
57:19 Q. And you found, with your other
57:20 authors, that there was no benefit of the filter?
57:21 A. Correct.
57:22 Q. That's an important finding.
57:23 Do you agree?

57:25 - 57:25 **D, ayala 03-21-2017 (00:00:01)** 03_20_18 combo final3_1.47

57:25 THE WITNESS: Yes.

58:8 - 58:11 **D, ayala 03-21-2017 (00:00:07)** 03_20_18 combo final3_1.48

58:8 Q. There was a study in 1998
58:9 by Dr. Decousus called the PREPIC 1 study.
58:10 Are you familiar with that study?
58:11 A. I am.

61:18 - 61:25 **D, ayala 03-21-2017 (00:00:21)** 03_20_18 combo final3_1.49

61:18 taking into account the lack of efficacy and the
61:19 fact there were no reduction in mortality in PREPIC
61:20 1 and PREPIC 2, coupled with the fact that the G2

Page/Line	Source	ID
	61:21 had a fivefold increased risk for fracture compared 61:22 to other filters. 61:23 BY MR. MATTHEWS: 61:24 Q. In 2007 would you have implanted that 61:25 filter?	
62:5 - 62:24	**D, ayala 03-21-2017 (00:01:08)** 62:5 THE WITNESS: The PREPIC 1 trial is a 62:6 great study, and it's a very interesting study. But 62:7 there are problems in this study, as there are 62:8 problems with every study. And the fundamental 62:9 problem that you have with this trial is that it 62:10 randomized patients who were candidates for caval 62:11 interruption or not; in other words, all patients 62:12 were treated with blood thinners. It doesn't really 62:13 address the question of what to do with those 62:14 patients that cannot be treated with blood thinners. 62:15 And from my review of the chart on 62:16 Ms. Booker, it was clear that she could not be 62:17 treated with blood thinners. The reason for that 62:18 was she had bleeding complications. She was, if I 62:19 recall, anemic, and she was to undergo subsequent 62:20 surgical interventions. 62:21 So her anticoagulation had to be 62:22 held, hence, PREPIC doesn't really apply to a 62:23 patient like Ms. Booker. It applies to a different 62:24 set of patients.	03_20_18 combo final3_1.50
62:25 - 63:20	**D, ayala 03-21-2017 (00:01:00)** 62:25 With regards to the Bard filter, 63:1 would I have used a different device if I knew at 63:2 the time that the Bard filter was not ideal or as 63:3 good as some of the other implants? The answer 63:4 would have to be yes. 63:5 BY MR. MATTHEWS: 63:6 Q. You would have used -- 63:7 A. I would have used a different filter 63:8 if there was a different filter that I knew of that 63:9 was better, in terms of its safety profile. 63:10 Q. In terms of the documents that you 63:11 have, I think they are Exhibit-2 and 3, the health 63:12 hazard report and then the investigation conducted	03_20_18 combo final3_1.51

Page/Line	Source	ID
	63:13 by Bard that showed a fivefold increased risk for 63:14 fracture and embolization of that fracture, and you 63:15 told us that would be the type of information you 63:16 would want to know in your benefit/risk analysis, 63:17 knowing that -- 63:18 A. Yes. 63:19 Q. -- and seeing that today, would that 63:20 have been enough to use another filter?	
63:22 - 64:2	**D, ayala 03-21-2017 (00:00:17)** 63:22 THE WITNESS: Difficult to say with 63:23 certainty. It would depend upon what other filters 63:24 we had at the time and what their problems would 63:25 have been. But it would have been a very important 64:1 piece of information, as far as making decisions 64:2 regarding this or any other patient, yes.	03_20_18 combo final3_1.52
64:4 - 64:7	**D, ayala 03-21-2017 (00:00:04)** 64:4 Q. And it would have influenced your 64:5 prescribing habit? 64:6 *** 64:7 THE WITNESS: Yes.	03_20_18 combo final3_1.53
64:9 - 64:10	**D, ayala 03-21-2017 (00:00:06)** 64:9 Q. Let me show you a study, I'm going to 64:10 mark this as D'Ayala Exhibit Number 7. And this is	03_20_18 combo final3_1.54
66:19 - 67:8	**D, ayala 03-21-2017 (00:00:52)** 66:19 Q. The conclusion of this study 66:20 by Dr. Nicholson and other doctors in different 66:21 fields of medicine found the Bard Recovery and Bard 66:22 G2 filters had high prevalence of fracture and 66:23 embolization with potentially life-threatening 66:24 sequelae. 66:25 Doctor, if you had been warned prior 67:1 to June of 2007 of this information, I know this is 67:2 dated 2010, but I'm going to ask you the question 67:3 for purposes of a hypothetical, that is, had you 67:4 known this information of this conclusion, that the 67:5 G2 had a high prevalence of fracture and 67:6 embolization with life-threatening sequelae, would 67:7 that have influenced your prescribing habits and the 67:8 use of the G2 with Ms. Booker?	03_20_18 combo final3_1.55
67:10 - 67:10	**D, ayala 03-21-2017 (00:00:02)**	03_20_18 combo final3_1.56

EXHIBIT C.1

March 22, 2018 P.M.

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

_____

In re: Bard IVC Filters, Products Liability Litigation	MD-15-02641-PHX-DGC
Sherr-Una Booker, an individual, Plaintiff, v. **C.R. Bard, Inc., a New Jersey corporation; and Bard Peripheral Vascular, Inc., an Arizona corporation,** Defendants.	Phoenix, Arizona March 22, 2018 1:00 p.m. CV-16-00474-PHX-DGC

BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

REPORTER'S TRANSCRIPT OF PROCEEDINGS

JURY TRIAL - DAY 6 P.M.

(Pages 1210 through 1322)

Official Court Reporter:
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Sandra Day O'Connor U.S. Courthouse
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Phoenix, Arizona 85003-2150
(602) 322-7245

Proceedings Reported by Stenographic Court Reporter
Transcript Prepared by Computer-Aided Transcription

Deposition Exhibit Number 3, and Trial Exhibit Number 905, Deposition Exhibit 19. 03:31:33

THE COURT: Any objection?

MS. HELM: No objection, Your Honor.

THE COURT: All right. Those are admitted. 03:31:45

(Exhibit Numbers 1130 and 905 were admitted into evidence.)

(Whereupon the video deposition of Robert Ferrara was played.)

MS. REED ZAID: Next witness appearing by videotape, which is only four minutes long, is Jason Greer. Jason Greer graduated from the University of Mississippi and became a sales representative at Bell South Mobility in 1991 and worked for two other companies doing sales until he joined Bard Peripheral Vascular in 1999 as a sales representative. In 2005 he became a district manager and throughout his time at Bard, he sold Bard's IVC filters. Mr. Greer left Bard in 2007 and currently works at another medical device manufacturer. 03:50:39 03:50:56

We would like to move one exhibit into evidence, Your Honor. It's Trial Exhibit 1912, Deposition Exhibit Number 7. 03:51:16

MS. HELM: Excuse me, Your Honor. No objection.

THE COURT: 1912 is admitted.

(Exhibit Number 1912 was admitted into evidence.)

MS. REED ZAID: Thank you.

Ladies and gentlemen, if you want to stand up while 03:51:45

C E R T I F I C A T E

I, ELAINE M. CROPPER, do hereby certify that I am duly appointed and qualified to act as Official Court Reporter for the United States District Court for the District of Arizona.

I FURTHER CERTIFY that the foregoing pages constitute a full, true, and accurate transcript of all of that portion of the proceedings contained herein, had in the above-entitled cause on the date specified therein, and that said transcript was prepared under my direction and control, and to the best of my ability.

DATED at Phoenix, Arizona, this 23rd day of March, 2018.

s/Elaine M. Cropper

Elaine M. Cropper, RDR, CRR, CCP

EXHIBIT C.2

Designation Run Report

Ferrara 04-07-17 Booker Depo Designations Final3

Ferrara, Robert 04-07-2017

Plaintiffs Designations 00:11:10

Plaintiffs Counters 00:00:49

Defense Designations 00:06:31

Total Time 00:18:30

Page/Line	Source	ID
	233:5 of discussing.	
233:12 - 233:17	**Ferrara, Robert 04-07-2017 (00:00:12)** 233:12 Q. Did you ever talk to Dr. 233:13 D'Ayala -- 233:14 A. D'Ayala. 233:15 Q. D'Ayala about caudal migration 233:16 with the G2? 233:17 A. I couldn't say specifically.	03_21_18 combo final3.49
249:17 - 249:19	**Ferrara, Robert 04-07-2017 (00:00:07)** 249:17 Q. Were you aware while you were 249:18 working at Bard that the G2 had more 249:19 caudal migrations than the Recovery?	03_21_18 combo final3.50
249:22 - 250:8	**Ferrara, Robert 04-07-2017 (00:00:24)** 249:22 A. I wasn't privy to the numbers 249:23 for both of them. So I wouldn't be privy 249:24 to any of that. 250:1 Q. So, the same would be true about 250:2 the more tilting and more perforations? 250:3 A. Any tilting or any perforation 250:4 rate I would not have specific access to. 250:5 Q. All right. So I would take it 250:6 from this answer you would have not been 250:7 able to relay that information to Dr. 250:8 D'Ayala?	03_21_18 combo final3.51
250:15 - 250:17	**Ferrara, Robert 04-07-2017 (00:00:05)** 250:15 A. I could not have passed 250:16 to Dr. D'Ayala any information that I 250:17 didn't have or was approved to give him.	03_21_18 combo final3.52
250:22 - 251:21	**Ferrara, Robert 04-07-2017 (00:00:52)** 250:22 Q. Have you ever heard of the 250:23 migration push test? 250:24 A. No. 251:1 Q. Are you aware of any kind of 251:2 test done by Bard to determine how much 251:3 force any of its filters could endure 251:4 before they migrated? 251:5 A. Anecdotally I may have heard 251:6 that they did some type of testing, but I 251:7 couldn't tell you any specifics. 251:8 Q. Were you ever given any	03_21_18 combo final3.53

EXHIBIT D

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UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

In Re Bard IVC Filters Products Liability Litigation	No. MD-15-02641-PHX-DGC
DORIS SINGLETON JONES, an individual, Plaintiff, v. C.R. BARD, INC., a New Jersey corporation and BARD PERIPHERAL VASCULAR, an Arizona corporation, Defendants.	**JOINT NOTICE OF FILING JURY INSTRUCTIONS** (The Honorable David G. Campbell)

In accordance with the Court's Order and Civil Minutes (Docs. 10587, 10805), the Parties hereby submit the following jury instructions for review at the May 4, 2018, final pretrial conference:

1. Agreed Preliminary Jury Instructions (Exhibit A);

2. Agreed Final Jury Instructions (Exhibit B);

3. Plaintiff's Proposed Jury Instructions (Exhibit C);

4. Defendants' Proposed Jury Instructions (Exhibit D);

5. Comprehensive Final Jury Instructions with Competing Instructions (Exhibit E).

[*The purpose of this document is to make it convenient for the Court and parties to have all of the instructions, including each party's proposed "competing" instructions in one place as the Court hears argument and considers which instructions to give.*]

RESPECTFULLY SUBMITTED this 1st day of May, 2018.

GALLAGHER & KENNEDY, P.A.

By: */s/ Mark O'Connor*
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Attorneys for C. R. Bard, Inc. and Bard Peripheral Vascular, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on this 1st day of May, 2018, I electronically transmitted the attached document to the Clerk's Office using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing.

/s/ Jessica Gallentine

Exhibit A

IN THE UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation, Doris Jones, an individual, Plaintiff, v. C. R. Bard, Inc., a New Jersey corporation; and Bard Peripheral Vascular, Inc., an Arizona corporation, Defendants.	No. MDL15-2641-PHX-DGC

AGREED PRELIMINARY JURY INSTRUCTIONS

DATED: May 1, 2018

David G. Campbell
United States District Judge

You are now the jury in this case and it is my duty to instruct you on the law. It your duty to find the facts from all of the evidence in the case. To those facts you will apply the law as I give it to you. You must follow the law as I give it to you, whether you agree with it or not, and you must not be influenced by any personal likes or dislikes, opinions, prejudices, or sympathy. That means that you must decide the case solely on the evidence before you. You will recall that you took an oath to do so.

At the end of the trial, I will give you final instructions. It is the final instructions that will govern your deliberations and your duties as jurors.

Please do not read into these instructions or the final instructions or anything I may say or do that I have an opinion regarding the evidence or what your verdict should be.

To help you follow the evidence, I will give you a brief summary of the positions of the parties. This is a personal injury case against a medical product manufacturer. The plaintiff, Doris Jones, had a Bard Eclipse filter placed in her inferior vena cava, which we'll refer to throughout the trial as the IVC, the vein that carries blood back to the heart. An IVC filter is intended to catch a blood clot before it reaches the heart or lungs. Defendants C.R. Bard, Inc., Bard Peripheral Vascular designed, manufactured and sold the Eclipse filter.

Mrs. Jones alleges that the filter was defectively designed and that the defendants failed to warn about its risks. She alleges that she was injured by the filter and she seeks to recover money from defendants to compensate for her injuries and to punish defendants for their allegedly wrongful conduct.

Defendants deny that their filter was defectively designed or that they failed to warn of its risks. Defendants contend that the risks associated with the Bard IVC filter are understood by the medical community and are considered by doctors when deciding whether to use them. Defendants assert that they are not responsible for any injuries or damages suffered by Mrs. Jones. There are two defendants in this case, C.R. Bard, Inc., and Bard Peripheral Vascular. From time to time the parties may refer to them as Bard or BPV.

You should decide the case as to each defendant separately. Unless otherwise stated, the instructions apply to all of the parties.

The evidence you are to consider in deciding what the facts are will consist of the sworn testimony of the witnesses, the exhibits that are admitted into evidence, any facts to which all of the lawyers have agreed, and those will be identified for you as agreed upon or stipulated facts, and any facts that I may instruct you to accept as proved.

In reaching your verdict, you may consider only the testimony and exhibits received in evidence. Certain things are not evidence and you may not consider them in deciding what the facts are. I will list them for you.

First, arguments and statements by lawyers are not evidence. The lawyers are not witnesses. What they may say in their opening statements this afternoon, their closing arguments at the end of the trial, or at other times is intended to help you interpret the evidence but it is not evidence.

If the facts as you remember them differ from the way the lawyers have stated them, your memory of the facts controls.

Second, questions and objections by lawyers are not evidence. Attorneys have a duty to their clients to object when they believe a question is improper under the rules and regulations of evidence. You should not be influenced by any lawyer's objection or by my ruling on it.

Third, testimony that is excluded or stricken or that I instruct you to disregard is not evidence and must not be considered. In addition, some evidence may be received only for a limited purpose. If I instruct to you consider certain evidence only for a limited purpose, you must do so and may not consider that evidence for any other purpose.

Finally, anything you may see or hear when the Court is not in session is not evidence. You are to decide the case solely on the evidence that will be received during the trial.

Evidence may be direct or circumstantial. Direct evidence is direct proof of a fact such as testimony by a witness about what that witness personally saw or heard or did. Circumstantial evidence is proof of one or more facts from which you can find another fact. You should consider both kinds of evidence. The law makes no distinction between the weight to be given to either direct or circumstantial evidence. It is for you to decide how much weight to give to any evidence.

There are Rules of Evidence that control what can be received into evidence during the trial. When a lawyer asks a question or offers an exhibit into evidence and a lawyer on the other side thinks that it is not permitted by the Rules of Evidence, that lawyer may object.

If I overrule the objection, the question may be answered or the exhibit received. If I sustain the objection, the question cannot be answered and the exhibit cannot be received. Whenever I sustain an objection to a question, you must ignore the question and must not guess at what the answer might have been.

Sometimes, as I've already indicated, I may order that evidence be stricken from the record and that you disregard or ignore that evidence. That means that when you are deciding the case, you must not consider the stricken evidence for any purpose.

In deciding the facts in this case, you may have to decide which testimony to believe and which testimony not to believe. You may believe everything a witness says or part of it or none of it.

In considering the testimony of any witness, you may take into account the opportunity and ability of the witness to see or hear or know the things testified to, the witness's memory, the witness's manner while testifying, the witness's interest in the outcome of the case if any, the witness's bias or prejudice if any, whether other evidence contradicted the witness's testimony, the reasonableness of the witness's testimony in light of all of the evidence, and any other factors that bear on believability.

Sometimes a witness may say something that is not consistent with something else he or she said. Sometimes different witnesses will give different versions of what happened. People often forget things and make mistakes in what they remember. Also, two people may see the same event but remember it differently. You may consider these differences but do not decide the testimony is untrue just because it differs from other testimony.

However, if you decide that a witness has deliberately testified untruthfully about something important, you may choose not to believe anything that witness said. On the other hand, if you think the witness testified untruthfully about some things but told the truth about others, you may accept the part you think is true and ignore the rest. The weight of the evidence as to a fact does not necessarily depend on the number of witnesses who testify about it. What is important is how believable the witnesses were and how much weight you think their testimony deserves.

I will now say a few words about your conduct as jurors. First, please keep an open mind throughout the trial and do not decide what the verdict should be until you and your fellow jurors have completed your deliberations at the end of the case.

Second, as I've already mentioned, because you must decide this case based only on the evidence received in the case and on my instructions as to the law that applies, you must not be exposed to any other information about the case or to the issues it involves during the course of your jury duty. Thus, until the end of the case or unless I instruct you otherwise, do not communicate with anyone in any way and do not let anyone else communicate with you in any way about the merits of the case or anything to do with it.

This includes discussing the case in person, in writing, by phone or electronic means, via email, text messaging or any Internet chat room, blog, website or application including, but not limited to, Facebook, YouTube, Twitter, Instagram, LinkedIn, Snapchat, or any other forms of social media.

This applies to communicating with your fellow jurors until I give you the case for deliberation, and it applies to communicating with everyone else, including your family

members, your employer, the media or press, and the people involved in the trial although, obviously, you can notify your family and your employer that you have been seated as a juror in this case and how long you expect the trial to last.

But if you are asked or approached in any way about your jury service or anything about this case, you must respond that you have been ordered not to discuss the matter and report the contact to the Court immediately.

Because you will receive all of the evidence and legal instruction you properly may consider to return a verdict during this trial, do not read, watch, or listen to any news or media accounts or commentary about the case or anything to do with it. Do not do any research such as consulting dictionaries, searching the Internet or using other reference materials and do not make any investigation or in any other way try to learn about the case on your own. Do not visit or view any place discussed in this case and do not use Internet programs or other devices to search for or view anyplace discussed during the trial.

Also, do not do any research about the case, the law, or the people involved including the parties, the witnesses, or the lawyers until you have been excused as jurors.

If you happen to read or hear anything touching on this case in the media, please turn away immediately and report the contact to me as soon as possible.

We have these rather detailed rules to protect each party's right to have this case decided only on the evidence that is presented here in court. Witnesses in court take an oath to tell the truth and the accuracy of their testimony is tested through the trial process.

If you do any research or investigation outside of the courtroom or gain any information through improper communication, then your verdict may be influenced by

inaccurate, incomplete or misleading information that has not been tested by the trial process. At least it will be based on information that these parties never had an opportunity to address during the trial. Each of the parties is entitled to a fair trial by an impartial jury and if you decide the case based on information not presented in the Court, you will have denied the parties a fair trial.

Please remember that you have taken an oath to follow these rules and it is very important that you do so.

A juror who violates these restrictions jeopardizes the fairness of this trial and a mistrial could result that would require the entire trial process to start over again. If any of you is exposed to any outside information, please notify me immediately.

I urge you to pay close attention to the trial testimony as it is given. When you deliberate at the end of the case, you will not have a transcript of what was said. Even though we have a court reporter taking down everything that is said, it takes several days after a trial is over for the court reporter to go back and clean up that transcript and compare it with the recording and get it completely accurate. And that process won't be finished by the time you're deliberating so you will not have a transcript of the trial and as a result, we urge you to pay close attention to the evidence as it is given.

If you wish, you may take notes to help you remember the evidence. If you do take notes, please keep them to yourself until you go to the jury room to decide the case. Do not let note-taking distract you. When you leave each day or during a break, your notes should be left in the courtroom on your chair. Nobody will read your notes. Whether or not you take notes, you should rely on your own memory of the evidence. Notes are only

to assist your memory. You should not be overly influenced by your notes or those of other jurors.

From time to time during the trial it may become necessary for me to talk to the lawyers outside of your hearing, either by having a conference here at the side of the bench as we did this morning or by calling a recess and excusing you from the courtroom. We will do our best to keep such conferences to a minimum. Please understand that the purpose of those conferences is not to keep relevant information from you, but to decide how certain evidence is to be treated under the Rules of Evidence and to avoid confusion and error.

I may not always grant a lawyer's request for a conference. Please do not consider my granting or denying a request for a conference as any indication of my opinion of what your verdict should be.

Trials proceed in the following way: First each side may make an opening statement. An opening statement is not evidence. It is simply an outline to help you understand what that party expects the evidence will show. The plaintiff will then present evidence and counsel for the defendant may cross-examine. Then the defendant may present evidence and counsel for the plaintiff may cross-examine.

After all of the evidence has been presented, I will give you instructions on the law that apply to this case and the attorneys will make their closing arguments. After that you will go to the jury room to deliberate on your verdict.

Counsel, are there any additions or corrections to the instructions?

Exhibit B

IN THE UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,

No. MDL15-2641-PHX-DGC

Doris Jones, an individual,

Plaintiff,

v.

C. R. Bard, Inc., a New Jersey corporation; and Bard Peripheral Vascular, Inc., an Arizona corporation,

Defendants.

AGREED FINAL JURY INSTRUCTIONS

DATED: May 1, 2018

David G. Campbell
United States District Judge

INSTRUCTION NO. 1

Members of the Jury: Now that you have heard all of the evidence, it is my duty to instruct you on the law that applies to this case.

A copy of these instructions will be sent to the jury room for you to consult during your deliberations.

It is your duty to find the facts from all the evidence in the case. To those facts you will apply the law as I give it to you. You must follow the law as I give it to you whether you agree with it or not. And you must not be influenced by any personal likes or dislikes, opinions, prejudices, or sympathy. That means that you must decide the case solely on the evidence before you. You will recall that you took an oath to do so.

Please do not read into these instructions or anything that I may say or do or have said or done as indicating that I have an opinion regarding the evidence or what your verdict should be.

INSTRUCTION NO. 2

Although there are two defendants in this case, C.R. Bard, Inc. and Bard Peripheral Vascular, Inc., you should decide the case as to the two defendants jointly. As a result, in these instructions and in the verdict form, we will refer to defendants collectively as "Bard." Unless otherwise stated, the instructions apply to both Bard and Mrs. Jones.

INSTRUCTION NO. 3

The evidence you are to consider in deciding what the facts are consists of:

1. the sworn testimony of the witnesses;

2. the exhibits that are admitted into evidence;

3. any facts to which the lawyers have agreed; and

4. any facts that I have instructed you to accept as proved.

INSTRUCTION NO. 4

In reaching your verdict, you may consider only the testimony of the witnesses, the exhibits received into evidence, and facts to which the parties have agreed.

Certain things are not evidence, and you may not consider them in deciding what the facts are. I will list them for you:

1. Arguments and statements by lawyers are not evidence. The lawyers are not witnesses. What they have said in their opening statements, may say in closing arguments and at other times is intended to help you interpret the evidence, but it is not evidence. If the facts as you remember them differ from the way the lawyers have stated them, your memory of the facts controls.

2. Questions and objections by lawyers are not evidence. Attorneys have a duty to their clients to object when they believe a question is improper under the rules of evidence. You should not be influenced by the objection or by the court's ruling on it.

3. Testimony that is excluded or stricken, or that you were instructed to disregard, is not evidence and must not be considered. In addition some evidence is received only for a limited purpose; when I instruct you to consider certain evidence only for a limited purpose, you must do so and you may not consider that evidence for any other purpose.

4. Anything you may have seen or heard when the court was not in session is not evidence. You are to decide the case solely on the evidence received during the trial.

INSTRUCTION NO. 5

Some exhibits admitted into evidence have been partially "redacted," which means that certain contents of the exhibits have been blacked out or whited out. The parties and I have redacted information that is not properly admitted as evidence. You may give the unredacted information in any exhibit whatever weight you choose, but you must disregard the redacted information and must not speculate about what it might say.

INSTRUCTION NO. 6

You have heard testimony from a number of witnesses who testified to opinions and the reasons for their opinions. This opinion testimony is allowed because of the education or experience of those witnesses.

Such opinion testimony should be judged like any other testimony. You may accept it or reject it, and give it as much weight as you think it deserves, considering the witness's education and experience, the reasons given for the opinion, and all the other evidence in the case.

INSTRUCTION NO. 7

Federal law prohibits current FDA employees from testifying in court regarding any function of the FDA, and prohibits current and former FDA employees from testifying about information acquired in the discharge of their official duties, without authorization of the Commissioner of the FDA. As a result, neither side in this case was able to present testimony from current FDA employees or former FDA employees regarding the discharge of their duties related to this case.

INSTRUCTION NO. 8

Certain charts and summaries not admitted into evidence have been shown to you in order to help explain the evidence in the case. These have been referred to as demonstrative exhibits. The demonstrative exhibits are only as good as the underlying evidence that supports them. You should, therefore, give them only such weight as you think the underlying evidence deserves.

INSTRUCTION NO. 9

Certain charts and summaries have been admitted into evidence to illustrate information brought out in the trial. Charts and summaries are only as good as the testimony or other admitted evidence that supports them. You should, therefore, give these only such weight as you think the underlying evidence deserves.

INSTRUCTION NO. 10.

All parties are equal before the law and a corporation is entitled to the same fair and conscientious consideration by you as any party.

INSTRUCTION NO. 11

Under the law, a corporation is considered to be a person. It can only act through its employees, agents, directors, or officers. Therefore, a corporation is responsible for the acts of its employees, agents, directors, and officers performed within the scope of authority.

INSTRUCTION NO. 12

Mrs. Jones asserts four claims against Bard: (1) Strict Product Liability Based on Design Defect; (2) Strict Product Liability Based on Failure to Warn; (3) Negligent Design; and (4) Negligent Failure to Warn. I will instruct you on the law that applies to each of these claims. You should consider each claim separately.

INSTRUCTION NO. 13

Before I give you instructions about Mrs. Jones' specific claims, let me give you a few instructions that will apply to all of the claims.

When a party has the burden of proving any claim or affirmative defense by a "preponderance of the evidence," it means you must be persuaded by the evidence that the claim or affirmative defense is more probably true than not true. You should base your decision on all of the evidence, regardless of which party presented it.

Some instructions will state that you must find that an event or condition or action was the "proximate cause" of Mrs. Jones' injury. Proximate cause means that cause which, in a natural and continuous sequence, produces an event, and without which cause such event would not have occurred. Thus, when I use the expression "proximate cause," I mean a cause that, in the natural or ordinary course of events, produced Mrs. Jones' injury.

In order to be a proximate cause, the act or omission complained of must be such that a person using ordinary care would have foreseen that the event, or some similar event, might reasonably result.

There may be more than one proximate cause of an event. Thus, to prove proximate cause, Mrs. Jones need not prove that an act or omission was the only cause or the last or nearest cause. It is sufficient if it combines with another cause resulting in the injury. However, if an act or omission of any person not a party to the suit was the sole proximate cause of an occurrence, then no act or omission of any party could have been a proximate cause.

STRICT LIABILITY FAILURE TO WARN

Mrs. Jones contends that Bard is strictly liable because it failed to give adequate warnings regarding the Eclipse IVC filter.

The manufacturer of a product that is sold as new property may be liable to any person who is injured because of an inadequate warning with respect to the product that existed at the time the manufacturer sold the product. However, a manufacturer of a product is not an insurer, and the fact that a product may cause an injury does not necessarily make the manufacturer liable.

The manufacturer of a medical device does not have a duty to warn the patient of the dangers involved with the product, but instead has a duty to warn the patient's doctor, who acts as a learned intermediary between the patient and the manufacturer.

To recover damages for strict liability based on an inadequate warning, Mrs. Jones must establish the following three elements by a preponderance of the evidence:

First, the warning given with the product was inadequate;

Second, the inadequate warning existed at the time the product left the control of Bard; and

Third, the inadequate warning was a proximate cause of Mrs. Jones' injury.

There is no single general way to define what constitutes an inadequate warning in a product. Whether or not a warning is inadequate is a question of fact to be determined by you, the jury, based on the instruction that I will give you and the evidence received during the trial.

Bard had a duty to give an adequate warning of known or reasonably foreseeable dangers arising from the use of its Eclipse IVC filter. Bard owes this duty to warn to all physicians whom the manufacturer should reasonably foresee may use the product. Bard's duty to warn may have been breached by:

a) failing to provide an adequate warning of the Eclipse filter's potential dangers or

b) failing to adequately communicate to Mrs. Jones' physicians the warning provided.

A manufacturer's duty to warn arises when the manufacturer knows or reasonably should know of the danger presented by the use of the product. Therefore, a manufacturer

has a continuing duty to adequately warn of defects in a product even after that product has left the control of the manufacturer.

You must decide whether adequate efforts were made by Bard to communicate all risks that were known or reasonably should have been known to Bard, to the physician who implanted the Eclipse filter in Mrs. Jones, and whether the warning that Bard communicated was adequate.

A product, however well or carefully made, that is sold without an adequate warning of such danger, may be said to be in a defective condition. If you find by a preponderance of the evidence that Bard did not adequately warn when an adequate warning should have been given, and that this inadequate warning proximately caused Mrs. Jones' injury, then you may find the Eclipse filter to be defective and for that reason, find that Mrs. Jones is entitled to recover damages.

ASSUMPTION OF RISK

Bard asserts an "assumption of the risk" defense. If Mrs. Jones knew of the Eclipse IVC filter's defect and was aware of the danger, but nevertheless proceeded unreasonably to make use of the product, taking a risk which in and of itself amounts to a failure to exercise ordinary care for her safety, she cannot later hold Bard responsible for any injury suffered due to taking such a risk.

To establish the defense of assumption of the risk, Bard must prove by a preponderance of the evidence that:

1) Mrs. Jones knew of the danger posed by the Eclipse IVC filter,

2) Mrs. Jones understood and appreciated the risks of that product, and

3) Mrs. Jones knowingly and voluntarily exposed herself to such a risk.

If you find that Bard has proved each of these elements by a preponderance of the evidence, then Mrs. Jones is not entitled to recover for the resulting injury or damages, and you should return a verdict for Bard.

PUNITIVE DAMAGES

In cases such as this, there may be aggravating circumstances that warrant the award of additional damages called punitive damages. Punitive damages are intended to punish, penalize, and deter wrongful conduct.

Before you may award punitive damages, Mrs. Jones must prove that the actions of Bard showed willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care that would raise the presumption of conscious indifference to consequences.

Mrs. Jones must make this proof by clear and convincing evidence. This is a different and higher burden of proof than a preponderance of the evidence, but is less than the standard of "beyond a reasonable doubt," which is the proof required in criminal cases. Clear and convincing evidence is defined as evidence that will cause you to firmly believe, to a high degree of probability, that the requirements for punitive damages have been proved.

If Mrs. Jones fails to prove by clear and convincing evidence that Bard was guilty of willful misconduct, malice, fraud, wantonness, oppression, or entire want of care that would raise the presumption of conscious indifference to consequences, then you may not award punitive damages. Mere negligence, even amounting to gross negligence, will not alone authorize an award of punitive damages.

In the verdict form, you will be asked to specify whether Mrs. Jones is entitled to recover punitive damages, but you will not yet be asked to determine an amount of punitive damages. If you decide that she should be awarded punitive damages, then you will receive some brief additional instructions, evidence, and argument before setting the amount.

There can be no recovery of punitive damages in this case unless there is first a recovery by Mrs. Jones of compensatory damages.

PROCESS OF DELIBERATIONS

Before you begin your deliberations, please elect one member of the jury as your presiding juror. The presiding juror will preside over the deliberations and serve as the spokesperson for the jury in court.

You shall diligently strive to reach agreement with all of the other jurors if you can do so. Your verdict must be unanimous.

Each of you must decide the case for yourself, but you should do so only after you have considered all of the evidence, discussed it fully with the other jurors, and listened to their views.

It is important that you attempt to reach a unanimous verdict but, of course, only if each of you can do so after having made your own conscientious decision. Do not be unwilling to change your opinion if the discussion persuades you that you should. But do not come to a decision simply because other jurors think it is right, or change an honest belief about the weight and effect of the evidence simply to reach a verdict.

INSTRUCTIONS FOR DELIBERATIVE PROCESS

Because you must base your verdict only on the evidence received in the case and on these instructions, I remind you that you must not be exposed to any other information about the case or to the issues it involves. Except for discussing the case with your fellow jurors during your deliberations:

> Do not communicate with anyone in any way and do not let anyone else communicate with you in any way about the merits of the case or anything to do with it. This includes discussing the case in person, in writing, by phone or electronic means, via email, via text messaging, or any internet chat room, blog, website or application, including but not limited to Facebook, YouTube, Twitter, Instagram, LinkedIn, Snapchat, or any other forms of social media. This applies to communicating with your family members, your employer, the media or press, and the people involved in the trial. If you are asked or approached in any way about your jury service or anything about this case, you must respond that you have been ordered not to discuss the matter and to report the contact to the court.
>
> Do not read, watch, or listen to any news or media accounts or commentary about the case or anything to do with it; do not do any research, such as consulting dictionaries, searching the Internet, or using other reference materials; and do not make any investigation or in any other way try to learn about the case on your own. Do not visit or view any place discussed in this case, and do not use Internet programs or other devices to search for or view any place discussed during the trial. Also, do not do any research about this case, the law, or the people involved – including the parties, the witnesses or the lawyers – until you have been excused as jurors. If you happen to read or hear anything touching on this case in the media, turn away and report it to me as soon as possible.

As I've explained before, these rules protect each party's right to have this case decided only on evidence that has been presented here in court. Witnesses here in court take an oath to tell the truth, and the accuracy of their testimony is tested through the trial process. If you do any research or investigation outside the courtroom, or gain any information through improper communications, then your verdict may be influenced by inaccurate, incomplete or misleading information that has not been tested by the trial process. Each of the parties is entitled to a fair trial by an impartial jury, and if you decide the case based on information not presented in court, you will have denied the parties a fair trial. Remember, you have taken an oath to follow the rules, and it is very important that you follow these rules.

A juror who violates these restrictions jeopardizes the fairness of these proceedings, and a mistrial could result that would require the entire trial process to start over. If any juror is exposed to any outside information, please notify the court immediately.

VIEWING EXHIBITS

The exhibits received in evidence that are capable of being displayed electronically will be provided to you in that form, and you will be able to view them in the jury room. A computer, projector, printer and accessory equipment will be available to you in the jury room.

A court technician will show you how to operate the computer and other equipment; how to locate and view the exhibits on the computer; and how to print the exhibits. You will also be provided with a paper list of all exhibits received in evidence. You may request a paper copy of any exhibit received in evidence by sending a note through the bailiff. If you need additional equipment or supplies or if you have questions about how to operate the computer or other equipment, you may send a note to the bailiff, signed by your presiding juror or by one or more members of the jury. Do not refer to or discuss any exhibit you were attempting to view.

If a technical problem or question requires hands-on maintenance or instruction, a court technician may enter the jury room with the bailiff present for the sole purpose of assuring that the only matter that is discussed is the technical problem. When the court technician or any non-juror is in the jury room, the jury shall not deliberate. No juror may say anything to the court technician or any non-juror other than to describe the technical problem or to seek information about operation of the equipment. Do not discuss any exhibit or any aspect of the case.

The sole purpose of providing the computer in the jury room is to enable you to view the exhibits received in evidence in this case. You may not use the computer for any other purpose. At my direction, technicians have taken steps to ensure that the computer does not permit access to the Internet or to any "outside" website, database, directory, game, or other material. Do not attempt to alter the computer to obtain access to such materials. If you discover that the computer provides or allows access to such materials, you must inform the court immediately and refrain from viewing such materials. Do not remove the computer or any electronic data from the jury room, and do not copy any such data.

COMMUNICATION WITH THE COURT

If it becomes necessary during your deliberations to communicate with me, you may send a note through the bailiff, signed by any one or more of you. No member of the jury should ever attempt to communicate with me except by a signed writing. I will not communicate with any member of the jury on anything concerning the case except in writing or here in open court with the parties present. If you send out a question, I will consult with the lawyers before answering it, which may take some time. You may continue your deliberations while waiting for the answer to any question. Please remember that you are not to tell anyone – including the court – how the jury stands, whether in terms of vote count or otherwise, until after you have reached a unanimous verdict or have been discharged. Do not disclose any vote count in any note you may send out to the Court.

VERDICT FORMS

A verdict form has been prepared for you. [*Explain verdict form as needed.*] After you have reached unanimous agreement on a verdict, your foreperson should complete the verdict form according to your deliberations, sign and date it, and advise the bailiff that you are ready to return to the courtroom.

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Exhibit C

IN THE UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation, Doris Jones, an individual, Plaintiff, v. C. R. Bard, Inc., a New Jersey corporation; and Bard Peripheral Vascular, Inc., an Arizona corporation, Defendants.	No. MDL15-2641-PHX-DGC

PLAINTIFF'S PROPOSED JURY INSTRUCTIONS NOT AGREED TO

DATED: May 1, 2018

David G. Campbell
United States District Judge

PLAINTIFF'S PROPOSED INSTRUCTION STRICT LIABILITY DESIGN

Mrs. Jones contends that Bard is strictly liable because of a defective design of the Eclipse IVC filter.

The manufacturer of a product that is sold as new property may be liable to any person who is injured because of a defect in the product that existed at the time the manufacturer sold the product. However, a manufacturer of a product is not an insurer, and the fact that a product may cause an injury does not necessarily make the manufacturer liable. To recover damages for strict product liability based on a design defect, Mrs. Jones must establish the following three elements by a preponderance of the evidence:

First, the product was defectively designed;

Second, the design defect existed at the time the product left the control of Bard; and

Third, the design defect in the product was a proximate cause of Mrs. Jones' injury.

There is not a single general way to define what constitutes a design defect in a product. Whether or not a product is defective is a question of fact to be determined by you, the jury, based on the instruction that I will give you and the evidence that has been received during the trial.

Although Bard is not required to ensure that a product design is incapable of producing injury, it has a duty to exercise reasonable care in choosing the design for a product.

To determine whether a product suffers from a design defect, you must balance the inherent risk of harm in a product design against the utility or benefits of that product design. You must decide whether the manufacturer acted reasonably in choosing a particular product design by considering all relevant evidence, including the following factors:

1) the usefulness of the product;

2) the severity of the danger posed by the design;

3) the likelihood of that danger;

4) the avoidability of the danger, considering the user's knowledge of the product, publicity surrounding the danger, the effectiveness of warnings, and common knowledge or the expectation of danger;

5) the user's ability to avoid the danger;

6) the technology available when the product was manufactured;

7) the ability to eliminate the danger without impairing the product's usefulness or making it too expensive;

8) the feasibility of spreading any increased cost through the product's price;

9) the appearance and aesthetic attractiveness of the product;

10) the product's utility for multiple uses;

11) the convenience and durability of the product;

12) alternative designs of the product available to the manufacturer; and

13) the manufacturer's compliance with industry standards or government regulations.

In determining whether a product was defectively designed, you may consider evidence of alternative designs that would have made the product safer and could have prevented or minimized Mrs. Jones' injury. In determining the reasonableness of the product design chosen by Bard, you should consider:

1) the availability of an alternative design at the time Bard designed this product;

2) the level of safety from an alternative design compared to the actual design;

3) the feasibility of an alternative design, considering the market and technology at the time the product was designed;

4) the economic feasibility of an alternative design;

5) the effect an alternative design would have on the product's appearance and utility for multiple purposes; and

6) any adverse effects on Bard or the product from using an alternative design.

If you decide that the risk of harm in the product's design outweighs the utility of that particular design, then the manufacturer exposed the consumer to greater risk of danger than the manufacturer should have in using that product design, and the product is defective. If after balancing the risks and utility of the product, you find by a preponderance of the evidence that the product suffered from a design defect that proximately caused Mrs. Jones' injury, then Mrs. Jones is entitled to recover damages.

Defendants' Objections:

Bard objects to Plaintiff's proposed charge because she has deleted two necessary elements from this instruction as given in *Booker*. First, Plaintiff deleted the paragraph that refers to considering compliance with industry standards or government regulations, which is an element of the risk utility test set forth by the Georgia Supreme Court, and for which a separate jury instruction was created. See, Ga. Civil Pattern Instruction 62.670 below:

62.670 **Strict Liability; Design Defect; Compliance with Industry Standards or Government Regulations**

In determining whether a product was defective, you may consider proof of a manufacturer's compliance with federal or state safety standards or regulations and industrywide customs, practices, or design standards. Compliance with such standards or regulations is a factor to consider in deciding whether the product design selected was reasonable considering the feasible choices of which the manufacturer knew or should have known. However, a product may comply with such standards or regulations and still contain a design defect.

Banks v. ICI Americas Inc., 264 Ga. 732 (1994)

Doyle v. Volkswagenwerk Artiengesellschaft, 267 Ga. 574 (1997)

Second, Plaintiff also deleted the paragraph regarding regulatory action. However, under Georgia law when a plaintiff claims a design defect in a widely-distributed product, "[t]he fact that . . . [defendant] had never been subjected to regulatory action with respect to the claimed defect . . . tends to negate the allegation that the configuration was a dangerous design." *Browning v. Paccar, Inc.*, 214 Ga. App. 496, 498, 448 S.E.2d 260, 263 (1994). As such, "evidence that the customary methods for protecting the public from defective [products] had not been instituted in connection with these [products] was relevant to show defendant's design and manufacture was not negligent." *Id.*

Defendants' proposed alternative is Defendants' Instruction on Design Defect

Plaintiff's Response:

For the reasons stated in Booker, Bard's proposed language provides undue emphasis on FDA evidence, drawing the jury's attention to FDA actions and inactions on three separate occasions. This results in an emphasis or comment on certain types of evidence as more important than other factors.

PLAINTIFF'S PROPOSED INSTRUCTION NEGLIGENT DESIGN

Mrs. Jones claims that Bard was negligent in the design of the Eclipse IVC filter she received. To recover on this claim, Mrs. Jones must prove by a preponderance of the evidence that:

(1) Bard had a duty of reasonable care to Mrs. Jones,

(2) Bard breached that duty in the design of the Eclipse filter,

(3) the breach was a proximate cause of Mrs. Jones' injury, and

(4) she suffered damages.

Reasonable care is that degree of care that is used by ordinarily careful manufacturers under the same or similar circumstances.

If Mrs. Jones has failed to prove any one of the four elements by a preponderance of the evidence, then you must find that Bard was not negligent in the design of the Eclipse filter she received.

Defendants' Objections:

Defendants acknowledge that Plaintiff's proposed instruction is the same as the one given in *Booker*. However, Defendants object to this this instruction on the grounds that it does not comply with Georgia law. See, *Ogletree v. Navistar International Transportation Corporation*, 271 Ga. 644 (1999), in which the Georgia Supreme Court held, "In a negligent design case, the risk-utility analysis applies to determine whether the manufacturer is liable. Thus, the mandate that a product's risk must be weighed against its utility incorporates the concept of 'reasonableness' so as to apply negligence principles in the determination of whether the manufacturer defectively designed its product." (Citations omitted)

Defendants' proposed alternative is Defendants' Proposed Instruction on negligent design.

Plaintiff's Response:

Plaintiff believes the instruction given in Booker was appropriate and avoids undue comment on the evidence of risk-benefit, which is but one of many factors a jury may consider in examining the evidence.

PLAINTIFF'S PROPOSED INSTRUCTION NEGLIGENT FAILURE TO WARN

Mrs. Jones claims that Bard was negligent in failing to warn about the risks of the Eclipse IVC filter she received. To recover on this claim, Mrs. Jones must prove by a preponderance of the evidence that:

(1) Bard had a duty of reasonable care to Mrs. Jones (via warnings to her physicians),

(2) Bard breached that duty in the adequacy of the warnings about the Eclipse filter,

(3) the breach was a proximate cause of the her injury, and

(4) she suffered damages.

A medical device manufacturer has a duty to warn physicians of a danger arising from use of a product once that danger becomes known to the manufacturer. Therefore, a manufacturer has a continuing duty to adequately warn of defects in a product even after that product has left the control of the manufacturer.

Reasonable care is the degree of care that is used by ordinarily careful manufacturers under the same or similar circumstances.

If Mrs. Jones has failed to prove any one of the four elements by a preponderance of the evidence, then you must find that Bard was not negligent in failing to warn about the risks of the Eclipse filter she received.

Source: Ga. Code Ann., § 51-1-11(C); Ford Motor Co. v. Reese, 684 S.E.2d 279, 284 (Ga. App. 2009).

Defendants' Objections:

Defendants object to this instruction as it is not a proper statement under Georgia law. Under Georgia law, whether premised on negligence or strict liability, Plaintiff must prove that "Bard had a duty to give an adequate warning of known or reasonably foreseeable dangers arising from the use of its filter. *Shelton v. GALCO Int'l, Ltd.*, No. 3:16-CV-00033-TCB, 2017 WL 3597497 (N.D. Ga. July 19, 2017) (quoting *Chrysler Corp. v. Batten*, 450 S.E.2d 208, 211 (Ga. 1994)) ("[T]he duty to warn arises whenever the manufacturer knows or reasonably should know of the danger arising from the use of the product."). Further, Plaintiff's reliance on *Battersby v. Boyer*, 526 S.E.2d 159, 162 (Ga. Ct. App. 1999) is misplaced. While the Georgia Courts acknowledge that there are

two separate causes of action, they also recognize that the same duty based elements apply to both strict liability and negligent failure to warn. J. Kennard Neal and Catherine Payne, *Ga. Products Liability Law* § 8:1 (4th ed. 2018) ("Georgia has traditionally recognized failure to warn claims arising both in negligence and in strict liability. [H]owever, Georgia courts make no distinction between the two, but apply the same duty concepts and the same tripartite test of foreseeability.") (citations omitted); *Id.* at § 2:1 ("[I]n examining either type of claim, Georgia courts have consistently applied the same duty-based negligence analysis.")

As to the duty owed to the physician, Defendants request that the same language used in the strict liability failure to warn be included.

Defendants' proposed alternative is Defendants' Proposed Instruction on negligent failure to warn.

Plaintiff's Response:

Plaintiff does not agree to Bard's proposed merger of the negligent failure to warn with the strict liability failure to warn instruction. Such theories of liability are separate and distinct, thus making the Booker instruction appropriate. *Battersby v. Boyer*, 526 S.E.2d 159, 162 (Ga. Ct. App. 1999).

DAMAGES

It is the duty of the court to instruct you about the measure of damages. By instructing you on damages, I do not mean to suggest for which party your verdict should be rendered.

If you find for Mrs. Jones on any or all of her claims, you must determine her damages. Mrs. Jones has the burden of proving damages by a preponderance of the evidence. It is for you to determine what damages, if any, have been proved. Your award must be based on evidence and not on speculation, guesswork or conjecture.

Damages are given as pay or compensation for injury done. Where one party is required to pay damages to another, the law seeks to ensure that the damages awarded are fair to both parties. If you find by a preponderance of the evidence that Mrs. Jones is entitled to recover damages, you should award to Mrs. Jones such sums as you believe are reasonable and just in this case.

Necessary expenses resulting from the injury are a legitimate item of damages. As to medical expenses, such as hospital, doctor, and medicine bills, the amount of the damage would be the reasonable value of such expense as was reasonably necessary.

Mrs. Jones seeks to recover not only for her past medical expenses, but also for medical expenses that may be incurred in the future. If you find that the evidence shows with reasonable certainty that Mrs. Jones will sustain future medical expenses proximately caused by the actions of Bard, and if you find that the evidence shows with reasonable certainty the amount of such future medical expenses, Mrs. Jones would be entitled to recover those amounts, reduced to present cash value.

Pain and suffering are recoverable as damages. The measure of damages for pain and suffering is left to the enlightened conscience of fair and impartial jurors. Questions of whether, how much, and how long Mrs. Jones has suffered or will suffer are for you to decide.

Pain and suffering include mental suffering, but mental suffering is not recoverable as damages unless there is also physical suffering. In evaluating Mrs. Jones' pain and suffering, you may consider the following factors, if proven:

(1) interference with normal living;

(2) interference with enjoyment of life;

(3) impairment of bodily health and vigor;

(4) fear of extent of injury;

(5) shock of impact;

(6) actual pain and suffering, past and future;

(7) mental anguish, past and future; and

(8) the extent to which Mrs. Jones must limit activities.

If you find that Mrs. Jones' pain and suffering will continue into the future, you should award such damages for future pain and suffering as you believe Mrs. Jones will endure. In making such an award, your standard should be your enlightened conscience as impartial jurors. You may take into consideration the fact that Mrs. Jones is receiving a present cash value award for damages not yet suffered.

Bard must take Mrs. Jones in whatever condition it finds her. A negligent actor must bear the risk that its liability will be increased by reason of the actual physical condition of the person toward whom its act is negligent. Thus, if you find that Mrs. Jones' injuries were increased by her existing physical condition, you may award damages for those increased injuries provided you find they were proximately caused by Bard.

Defendants' Objection:

Defendants object to the last paragraph as it is not conformed to the evidence in this case. There is no evidence or testimony that any actions of Bard caused or contributed to Ms. Jones' existing medical conditions.

Plaintiff's Response:

To the extent Bard is allowed to introduce evidence of Plaintiff's unrelated medical conditions or allegedly acting against medical advice, the limiting paragraph is important to clarify for the jury that the defendant takes the victim as it finds her. If Plaintiff's MIL Nos. 1-3 are granted, Plaintiff will agree to withdraw the last paragraph.

PLAINTIFF'S PROPOSED INSTRUCTION RE PUNITIVE DAMAGES

Members of the jury, you have decided that Mrs. Jones should be awarded punitive damages. In order to determine the amount of punitive damages, the parties have presented evidence and will now present brief arguments.

The measure of punitive damages is your enlightened conscience as an impartial jury. Any award you make should be both reasonable and just in light of your previous award of compensatory damages, the conduct and circumstances of Bard, and the purpose of punitive damages.

In considering the amount of punitive damages, you may consider the following factors:

1) the nature and reprehensibility of Bard's conduct;

2) the extent and duration of Bard's wrongdoing and the likelihood of its recurrence;

3) the intent of Bard in committing the wrong;

4) the profitability of Bard's wrongdoing;

5) the amount of compensatory damages you have previously awarded;

6) the financial circumstances, that is, the financial condition or the net worth of Bard.

In making an award of punitive damages, you should consider the degree of reprehensibility of Bard's wrongdoing. You should consider all of the evidence, both aggravating and mitigating, to decide how much punishment, penalty, or deterrence Bard's conduct deserves in the form of punitive damages. In assessing reprehensibility, you may consider whether:

1) the harm caused was physical, as opposed to economic;

2) the conduct showed an indifference to or a reckless disregard of the health or safety of others; and

3) the conduct involved repeated actions or was an isolated incident.

You may have heard evidence of other conduct and procedures of Bard. For the purpose of punitive damages, you may not consider evidence of any conduct of Bard that

is dissimilar to that which resulted in Mrs. Jones' injury – unless such dissimilar conduct was related to the specific harm suffered by Mrs. Jones in this case.

Defendants' Objections:

Defendants acknowledge that Plaintiff's proposed instruction is the same as the one that was given in *Booker*; however, Defendants object to this charge because it does not comply with the US Supreme Court decisions on punitive damages. See, State *Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408 (2003); *BMW of N. Am., Inc. v. Gore*, 517 U.S. 559 (1996); *Dimaso v. Ford Motor Company, et. al.*, No. 99-A-6172-6, 2003 WL 22850075, at *1 (Ga. Super. 2003); *Hockensmith v. Ford Motor Co.*, No. 1:01-CV-3645G, 2003 WL 25639639, at *10 (N.D. Ga. Apr. 17, 2003). See also Georgia Suggested Pattern Jury Instructions, Vol. I: Civil Cases, No. 66.770-66.780 (5th ed. 2016).

Defendants' proposed alternative is Defendants' Proposed Instruction A regarding punitive damages.

Plaintiff's Response:

For the reasons stated in Plaintiff's response to Bard's new charge on punitive damages, Plaintiff maintains that the Booker instruction accurately stated the law and is appropriate for this case.

PLAINTIFF'S REQUESTED FDA LIMITING INSTRUCTION

The FDA's review of a medical device depends upon how the device is classified under FDA regulations.

Certain devices are reviewed under FDA's Pre-Market Approval (PMA) process, which approves products focusing on a device's "safety and efficacy."

The FDA's 510(k) process determines whether a device is "substantially equivalent" to another device already legally on the market., it does not evaluate devices for safety and efficacy.

Bard's IVC filters, including Doris Jones' Eclipse IVC filter, were not FDA approved through the PMA process, but were cleared by the FDA through its 510(k) process.

Defendants' Objections:

Defendants object to this instruction on the grounds that it is a comment on facts that should be testified to by witnesses or presented through exhibits. Defendants do not offer an alternative instruction as they do not believe that a statement on the facts or evidence is appropriate

Plaintiff's Response:

Plaintiff responds that this instruction is likely to be appropriate given the emphasis at trial on FDA activity with respect to filter clearance. In submitting this instruction, Plaintiff understands that the Court will evaluate the evidence at trial to determine whether such an instruction is necessary.

PLAINTIFF'S PROPOSED INSTRUCTION RE MANUFACTURER'S SCOPE OF KNOWLEDGE

PRODUCTS LIABILITY – DEFECT DUE TO INADEQUATE WARNING; MANUFACTURER HELD TO THE KNOWLEDGE AND SKILL OF AN EXPERT

In cases such as the instant case, a manufacturer is held to the knowledge and skill of an expert. This is relevant in determining (1) whether the manufacturer knew or should have known of a danger in its product and (2) whether the manufacturer was negligent in failing to communicate this superior knowledge. The manufacturer's status as an expert means that at a minimum, it must keep abreast of scientific knowledge, discoveries, and advances and is presumed to know what is imported thereby.

Even more importantly, a manufacturer has a duty to test and inspect its product. The extent of research and experiment must be commensurate with the dangers involved. A product must not be made available without disclosures of these dangers that the application of reasonable foresight would reveal. Nor, may a manufacturer rely unquestioningly on others to sound such disclosure concerning a danger in this product. Rather, each manufacturer must bear the burden of showing that its own conduct was proportionate to the scope of its duty.

Borel v. Fibreboard Paper Prods., Corp., 493 F 2d 1076, 1080-1090 (5th Circuit);
The Corporation of Mercer University v. National Gypsum Co., et al., 1986 WL 12445 (M.D. Ga. 1986).

Defendants' Objections:

Defendants object to this instruction on the grounds that it is not a proper statement of Georgia law. The cases cited by Plaintiff do not apply to this case. *Borel v. Fibreboard Paper Prods, Corp*. 493 F. 2d 1076 (1973) applies Texas law. Plaintiff cites no case that stands for this proposition under Georgia law. In addition, *The Corporation of Mercer University v. National Gypsum Co*, 1986 WL 12445 (M.D. Ga. 1986) is not applicable. It was a property damage claim over the removal of asbestos and does not stand for the proposition stated in the charge. The charge expands the duty of a manufacturer beyond what is required by Georgia law. The Court refused to give this instruction in *Booker*.

Defendants propose as alternative instruction their proposed instructions on strict liability and negligent failure to warn.

Plaintiff's Response:

The law is correctly stated as set forth in *Mercer, supra*. While Mercer was an asbestos case, it stands for the unremarkable and unsurprising proposition that

manufacturers of products should, at a minimum, be aware of the knowledge available in the scientific community concerning their products. *Id.* at *2.

PLAINTIFF'S PROPOSED INSTRUCTION RE SCOPE OF DUTY TO WARN

PRODUCTS LIABILITY – MANUFACTURER'S DUTY TO WARN

You must decide whether adequate efforts were made by Bard to communicate all risks that were known to Bard or reasonably should have been known to Bard to the physician who implanted the Eclipse Filter in Mrs. Jones, and whether the warning that Bard communicated was adequate. A warning is inadequate if it does not provide a complete disclosure of both the existence of the risk and the extent of the danger and the severity of any potential injury involved.

Chrysler Corp. v. Batten, 264 Ga. 723, 724 (1994);
Ford Motor Co. v. Stubblefield, 171 Ga. App. 331, 335 (1984);
Watkins v. Ford Motor Co., 190 F. 3d 1213, 1220 (11th Cir. 1999);
Stapleton v. Kawasaki Heavy Indus., Inc., 608 F.2d 571, 573 (5th Cir. 1979);
White v. W.G.M. Safety Corp., 707 F. Supp. 544, 549 (S.D. Ga. 1988);
Bryant v. Hoffman-La Roche, Inc., 262 Ga. App. 401, 410 (2003);
Sands v. Kawasaki Motors Corp., 2009 WL 3152859, at *5 (S.D. Ga. Sept. 30, 2009).

Defendants' Objections:

Defendants object to this instruction on the grounds that it is not a proper statement of Georgia law and attempts to extend the duty to warn beyond what is required. It is also duplicative of the instruction on failure to warn and will confuse the jury. Further in a case involving a learned intermediary, the fact the risks were known in the medical community is a factor that should be considered by the jury. *See Wheat v. Sofamor, S.N.C.*, 46 F.Supp.2d 1351, 1363 (N.D.Ga.1999) and *Ellis. C.R. Bard, Inc.*, 311 F.3d 1272 (2002). The Court declined to give this instruction in *Booker.*

Defendants propose as alternative instructions their proposed instructions on strict liability and negligent failure to warn. If the Court is inclined to give this instruction in addition to those, Defendants propose as an alternative instruction:

You must decide whether adequate efforts were made by Bard to communicate the risks that were known to Bard or reasonably should have been known to Bard to the physician who implanted the Eclipse Filter in Ms. Jones, and whether the warning that Bard communicated was adequate. However, in making that determination you make take into account whether the risks were generally known by Dr. Avino and the medical community generally.

Plaintiff's Response:

The proposed instruction correctly states the law and simply advises the jury that a warning that is inadequate if it does not fully disclose the risks and the extent of the danger. Plaintiff does not object to a modification of the instruction to clarify that the warning must be to physicians, not patients, but believes this topic is adequately covered in other instructions.

PLAINTIFF'S PROPOSED INSTRUCTION RE RISKS TO BE WARNED ABOUT

PRODUCTS LIABILITY – DUTY TO WARN OF KNOWN DANGERS AND DANGERS THAT SHOULD HAVE BEEN KNOWN

In considering whether Bard violated its duty to warn, you may consider not only what dangers Bard knew at the time the product was sold, but also what Bard should have known at that time by the application of reasonable, developed human skill.

Bishop v. Farhat, 227 Ga. App. 201, 206 (1997).

Defendants' Objections:

Defendants object to this instruction on the grounds that it is duplicative of the proposed instructions on strict liability and negligent failure to warn. This charge is a paraphrase from *Bishop v. Farhat*, which actually cites to *Chrysler Corp. v Batten*, 264 Ga. 723 (1994). The Georgia Pattern Instruction on strict liability failure to warn is likewise taken from *Batten*. Therefore, there is no need for an additional charge.

Plaintiff's Response:

This instruction is helpful to the jury in understanding the contours of the failure to warn claim and merely instructs (accurately) on the law imposing the duty to warn on Bard.

Exhibit D

IN THE UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation, _____ Doris Singleton Jones, an individual, Plaintiff, v. C. R. Bard, Inc., a New Jersey corporation; and Bard Peripheral Vascular, Inc., an Arizona corporation, Defendants.	No. MDL15-2641-PHX-DGC

DEFENDANTS' PROPOSED JURY INSTRUCTIONS

DATED: May 1, 2018

DEFENDANTS' PROPOSED INSTRUCTION STRICT LIABILITY DESIGN

Mrs. Jones contends that Bard is strictly liable because of a defective design of the ECLIPSE IVC filter.

The manufacturer of a product that is sold as new property may be liable to any person who is injured because of a defect in the product that existed at the time the manufacturer sold the product. However, a manufacturer of a product is not an insurer, and the fact that a product may cause an injury does not necessarily make the manufacturer liable. To recover damages for strict product liability based on a design defect, Mrs. Jones must establish the following three elements by a preponderance of the evidence:

First, the product was defectively designed;

Second, the design defect existed at the time the product left the control of Bard; and

Third, the design defect in the product was a proximate cause of Mrs. Jones' injury.

There is not a single general way to define what constitutes a design defect in a product. Whether or not a product is defective is a question of fact to be determined by you, the jury, based on the instruction that I will give you and the evidence that has been received during the trial.

Although Bard is not required to ensure that a product design is incapable of producing injury, it has a duty to exercise reasonable care in choosing the design for a product.

To determine whether a product suffers from a design defect, you must balance the inherent risk of harm in a product design against the utility or benefits of that product design. You must decide whether the manufacturer acted reasonably in choosing a particular product design by considering all relevant evidence, including the following factors:

1) the usefulness of the product;

2) the severity of the danger posed by the design;

3) the likelihood of that danger;

4) the avoidability of the danger, considering the user's knowledge of the product, publicity surrounding the danger, the effectiveness of warnings, and common knowledge or the expectation of danger;

5) the user's ability to avoid the danger;

6) the technology available when the product was manufactured;

7) the ability to eliminate the danger without impairing the product's usefulness or making it too expensive;

8) the feasibility of spreading any increased cost through the product's price;

9) the appearance and aesthetic attractiveness of the product;

10) the product's utility for multiple uses;

11) the convenience and durability of the product;

12) alternative designs of the product available to the manufacturer; and

13) the manufacturer's compliance with industry standards or government regulations.

In determining whether a product was defectively designed, you may consider evidence of alternative designs that would have made the product safer and could have prevented or minimized Mrs. Jones' injury. In determining the reasonableness of the product design chosen by Bard, you should consider:

1) the availability of an alternative design at the time Bard designed this product;

2) the level of safety from an alternative design compared to the actual design;

3) the feasibility of an alternative design, considering the market and technology at the time the product was designed;

4) the economic feasibility of an alternative design;

5) the effect an alternative design would have on the product's appearance and utility for multiple purposes; and

6) any adverse effects on Bard or the product from using an alternative design.

In determining whether a product was defective, you may consider proof of a manufacturer's compliance with federal or state safety and non-safety standards or regulations and industrywide customs, practices, or design standards. Compliance with such standards or regulations is a factor to consider in deciding whether the product design selected was reasonable considering the feasible choices of which the manufacturer knew or should have known. However, a product may comply with such standards or regulations and still contain a design defect.

In deciding whether the design of the ECLIPSE filter was defective, you may also consider whether the FDA instituted regulatory action with respect to the ECLIPSE filter. However, a product may be defective even if the FDA institutes no regulatory action.

If you decide that the risk of harm in the product's design outweighs the utility of that particular design, then the manufacturer exposed the consumer to greater risk of danger than the manufacturer should have in using that product design, and the product is defective. If after balancing the risks and utility of the product, you find by a preponderance of the evidence that the product suffered from a design defect that proximately caused Mrs. Jones' injury, then Mrs. Jones is entitled to recover.

Plaintiff's Objection:

The instruction places undue emphasis on FDA evidence, focusing the jury's attention on FDA action or inaction on three separate occasions.

Defendants' Response:

This is the instruction given in *Booker* with only the name and product name changed. As is stated in Defendants' objection to Plaintiff's proposed instruction, Plaintiff deleted two necessary elements from the instruction, the Georgia Pattern Instruction on compliance with industry standards and the language reflecting Georgia law regarding regulatory action. Defendants incorporate their objection to Plaintiff's proposed instruction on strict liability design.

DEFENDANTS' PROPOSED INSTRUCTION NEGLIGENT DESIGN

Mrs. Jones claims that Bard was negligent in the design of the ECLIPSE IVC filter she received. To recover on this claim, Mrs. Jones must prove by a preponderance of the evidence that:

(1) Bard had a duty of reasonable care to Mrs. Jones,

(2) Bard breached that duty in the design of the ECLIPSE filter,

(3) the breach was a proximate cause of Mrs. Jones' injury, and

(4) she suffered damages.

Reasonable care is that degree of care that is used by ordinarily careful manufacturers under the same or similar circumstances. In making the determination of whether Bard acted reasonably, you should consider the risk-benefit analysis for design defect about which I previously instructed you.

If Mrs. Jones has failed to prove any one of the four elements by a preponderance of the evidence, then you must find that Bard was not negligent in the design of the ECLIPSE filter she received.

Plaintiff's Objection:

Plaintiff proposes that the instruction from Booker be given, with name and product information modified. Bard's proposed language would confuse the negligent design instruction with the strict product liability instruction making risk/benefit a de facto element of both claims and unnecessarily emphasizing this aspect of the claim.

Defendants' Response:

Defendants request that this language be added to make the instruction consistent with Georgia law. See, *Ogletree v. Navistar International Transportation Corporation*, 271 Ga. 644 (1999), in which the Georgia Supreme Court held, "In a negligent design case, the risk-utility analysis applies to determine whether the manufacturer is liable. Thus, the mandate that a product's risk must be weighed against its utility incorporates the concept of "reasonableness" so as to apply negligence principles in the determination of whether the manufacturer defectively designed its product. (Citations omitted)"

DEFENDANTS' PROPOSED INSTRUCTION NEGLIGENT FAILURE TO WARN

Mrs. Jones claims that Bard was negligent in failing to warn Dr. Avino about the risks of the ECLIPSE IVC filter he implanted in Ms. Jones. To recover on this claim, Mrs. Jones must prove by a preponderance of the evidence that:

(1) Bard had a duty of reasonable care to Mrs. Jones,

(2) Bard breached that duty in the adequacy of the warnings about the ECLIPSE filter provided to Dr. Avino,

(3) the breach was a proximate cause of the her injury, and

(4) she suffered damages.

Reasonable care is that degree of care that is used by ordinarily careful manufacturers under the same or similar circumstances. In making the determination of whether Bard acted reasonably in warning Dr. Avino, you should consider the same factors for strict liability failure to warn about which I previously instructed you.

The manufacturer of a medical device does not have a duty to warn the patient of the dangers involved with the product, but instead has a duty to warn the patient's doctor, who acts as a learned intermediary between the patient and the manufacturer.

If Mrs. Jones has failed to prove any one of the four elements by a preponderance of the evidence, then you must find that Bard was not negligent in failing to warn about the risks of the ECLIPSE filter she received.

Plaintiff's Objection:

Plaintiff objects only to the highlighted text. The proposed reference back to the strict liability instruction will be confusing to the jury since it would send the message that it is deciding the same issue for both claims when such claims are separate and distinct. *Battersby v. Boyer*, 526 S.E.2d 159, 162 (Ga. Ct. App. 1999).

Defendant's Response:

Defendants request these revisions to the instruction given in *Booker* to comply with Georgia law. Under Georgia law, whether premised on negligence or strict liability, Plaintiff must prove that "Bard had a duty to give an adequate warning of known or reasonably foreseeable dangers arising from the use of its filter. *Shelton v. GALCO Int'l*,

Ltd., No. 3:16-CV-00033-TCB, 2017 WL 3597497 (N.D. Ga. July 19, 2017) (quoting *Chrysler Corp. v. Batten*, 450 S.E.2d 208, 211 (Ga. 1994)) ("[T]he duty to warn arises whenever the manufacturer knows or reasonably should know of the danger arising from the use of the product."). Further, Plaintiff's reliance on *Battersby v. Boyer*, 526 S.E.2d 159, 162 (Ga. Ct. App. 1999) is misplaced. While the Georgia Courts acknowledge that there are two separate causes of action, they also recognize that the same duty based elements apply to both strict liability and negligent failure to warn. J. Kennard Neal and Catherine Payne, *Ga. Products Liability Law* § 8:1 (4th ed. 2018) ("Georgia has traditionally recognized failure to warn claims arising both in negligence and in strict liability. [H]owever, Georgia courts make no distinction between the two, but apply the same duty concepts and the same tripartite test of foreseeability.") (citations omitted); *Id.* at § 2:1 ("[I]n examining either type of claim, Georgia courts have consistently applied the same duty-based negligence analysis.")

Also, and importantly, the instruction as previously written is confusing because it refers to a duty to the "Plaintiff," but in the context of a medical device the duty is to the implanting physician. *McCombs v. Synthes*, 277 Ga. 252, 253, 587 S.E.2d 594 (2003). If learned intermediary is not included in both the strict liability and negligent failure to warn instructions, Defendants request that it be given as a separate instruction as set forth below.

LEARNED INTERMEDIARY

The manufacturer of a medical device does not have a duty to warn the patient of the dangers involved with the product, but instead has a duty to warn the patient's doctor, who acts as a learned intermediary between the patient and the manufacturer.

McCombs v. Synthes, 277 Ga. 252, 253, 587 S.E.2d 594 (2003)

DEFENDANTS' REQUEST FOR INSTRUCTION
FAILURE TO READ WARNING

If a physician does not actually read a warning provided by the manufacturer of a medical device, the adequacy or lack of adequacy of that warning cannot be the proximate cause of the plaintiff's injuries.

Plaintiff's Objection:

This instruction is unnecessary and improper. Questions of causation are for the jury. In addition, Bard had a continuing duty to warn of dangers under Georgia law. Issuance of post-implantation warnings could have allowed for retrieval of Mrs. Jones' filter before it fractured. Ga. Code Ann., Section 51-1-11(C). Further, the instruction is an improper comment on the evidence. It also will be confusing since Dr. Avino testified that he read the IFUs for Bard devices and, even if a jury assumes they are predecessor devices, the warnings are the same for the Eclipse IFU.

Defendants' Response:

Under Georgia law, the failure to warn claim can be based on either the adequacy of the warning or the adequacy of the attempts to communicate the warning. Failure to read a warning prevents recovery on the first part of the claim. "[F]ailure to read instructions or printed warnings will prevent a plaintiff from recovering on a claim grounded on failure to provide adequate warning of the product's potential risk." *Wilson Foods Corp. v. Turner*, 218 Ga. App. 74, 75, 460 S.E.2d 532, 534 (1995); *Camden Oil Co., LLC v. Jackson*, 609 S.E.2d 356, 358 (Ga. App. 2004) ("where a plaintiff does not read an allegedly inadequate warning, the adequacy of the warning's contents cannot be a proximate cause of the plaintiff's injuries"). The evidence in the case is that the Eclipse IFU contains different (and contained additional) warnings than the predecessor devices.

DEFENDANTS' REQUEST FOR INSTRUCTION
JURY DELIBERATION; PRODUCT DEFECT

If you find by a preponderance of the evidence that the product was defective in design or the adequacy of the warning provided when it left the control of the manufacturer and that the plaintiff's injury was proximately caused by that defect, then you would return a verdict for the plaintiff, unless the plaintiff is denied recovery under some other principle of law given to you in these charges.

If after considering all the evidence, you do not believe by a preponderance of the evidence that the product by which plaintiff claims to have been injured was defective in design or adequacy of the warning when it left the manufacturer's control or that the product was the proximate cause of the plaintiff's injury, then you would end your deliberations; the plaintiff would not be entitled to recover; and you would return a verdict for the defendant.

Georgia Pattern Instruction 62.720 Jury Deliberation; Product Defect

Plaintiff's Objection:

This instruction is unnecessary in light of other final instructions given to the jury. In addition, it is confusing and risks having the jury believe that it must find for Plaintiff on all claims to render a verdict (or both design or both warning claims). There are *four* separate claims and a jury need only find for Plaintiff on *one* of these claims. This instruction muddles that fact.

Defendants' Response:

This is a Georgia pattern instruction that is not encompassed in the instructions as given and provides the jury with necessary guidance on how to proceed during their deliberations.

DEFENDANT'S PROPOSED INSTRUCTION DAMAGES

It is the duty of the court to instruct you about the measure of damages. By instructing you on damages, I do not mean to suggest for which party your verdict should be rendered.

If you find for Mrs. Jones on any or all of her claims, you must determine her damages. Mrs. Jones has the burden of proving damages by a preponderance of the evidence. It is for you to determine what damages, if any, have been proved. Your award must be based on evidence and not on speculation, guesswork or conjecture.

Damages are given as pay or compensation for injury done. Where one party is required to pay damages to another, the law seeks to ensure that the damages awarded are fair to both parties. If you find by a preponderance of the evidence that Mrs. Jones is entitled to recover damages, you should award to Mrs. Jones such sums as you believe are reasonable and just in this case.

Necessary expenses resulting from the injury are a legitimate item of damages. As to medical expenses, such as hospital, doctor, and medicine bills, the amount of the damage would be the reasonable value of such expense as was reasonably necessary.

Mrs. Jones seeks to recover not only for her past medical expenses, but also for medical expenses that may be incurred in the future. If you find that the evidence shows with reasonable certainty that Mrs. Jones will sustain future medical expenses proximately caused by the actions of Bard, and if you find that the evidence shows with reasonable certainty the amount of such future medical expenses, Mrs. Jones would be entitled to recover those amounts, reduced to present cash value.

Pain and suffering are recoverable as damages. The measure of damages for pain and suffering is left to the enlightened conscience of fair and impartial jurors. Questions of whether, how much, and how long Mrs. Jones has suffered or will suffer are for you to decide.

Pain and suffering include mental suffering, but mental suffering is not recoverable as damages unless there is also physical suffering. In evaluating Mrs. Jones' pain and suffering, you may consider the following factors, if proven:

(1) interference with normal living;

(2) interference with enjoyment of life;

(3) impairment of bodily health and vigor;

(4) fear of extent of injury;

(5) shock of impact;

(6) actual pain and suffering, past and future;

(7) mental anguish, past and future; and

(8) the extent to which Mrs. Jones must limit activities.

If you find that Mrs. Jones' pain and suffering will continue into the future, you should award such damages for future pain and suffering as you believe Mrs. Jones will endure. In making such an award, your standard should be your enlightened conscience as impartial jurors. You may take into consideration the fact that Mrs. Jones is receiving a present cash value award for damages not yet suffered.

Plaintiff's Objection:

This instruction omits an important paragraph advising the jury that Bard must take the Plaintiff as it finds her and is not relieved of liability by virtue of any pre-existing conditions Plaintiff has. The Booker instruction adequately addresses this situation and merely sets forth a correct statement of the law.

Defendants' Response:

Defendants deleted and object to the last paragraph of the instruction given in *Booker* as not conformed to the evidence in this case. There is no evidence or testimony that any actions of Bard caused or contributed to Ms. Jones' existing medical conditions.

DEFENDANTS' REQUEST FOR INSTRUCTION
TORT DAMAGES; DUTY TO LESSEN

When a person is injured by the negligence of another, she must mitigate her damages as much as is practicable by the use of ordinary care and diligence.

If you find that plaintiff has suffered damages as alleged, under the law, she is bound to reduce those damages, as much as is practicable, by the use of ordinary care. If you believe that by the use of such care that she could have reduced the damages, you would determine to what extent and reduce such damages to that extent.

Georgia Pattern Instruction 66.015 Tort Damages; Duty to Lessen

Plaintiff's Objection:

There is no evidence supporting Mrs. Jones' alleged failure to mitigate her damages. Thus, instructing the jury on this issue will be confusing and contrary to the evidence. See also Plaintiff MILs 1-3.

Defendants' Response:

Plaintiff claims several alleged injuries for which she has received medical care and instruction that she has failed to follow. To the extent that she attributes those to the filter, her failure to follow medical advice or seek medical attention is relevant. O.C.G.A. §51-12-11*; Mallock v. Kicklighter*, 10 Ga. App. 605 (1912).

DEFENDANTS' PROPOSED INSTRUCTION A – PUNITIVE DAMAGES

Members of the jury, you have decided that Mrs. Jones should be awarded punitive damages. In order to determine the amount of punitive damages, the parties have presented evidence and will now present brief arguments.

The measure of punitive damages is your enlightened conscience as an impartial jury. Any award you make should be both reasonable and just in light of your previous award of compensatory damages, the conduct and circumstances of Bard, and the purpose of punitive damages.

In considering the amount of punitive damages, you may consider the following factors:

1) the nature and reprehensibility of Bard's conduct;

2) the extent and duration of Bard's wrongdoing and the likelihood of its recurrence;

3) the intent of Bard in committing the wrong;

4) the profitability of Bard's wrongdoing in Georgia;

5) the amount of compensatory damages you have previously awarded;

6) the financial circumstances, that is, the financial condition or the net worth of Bard based on the sale of Eclipse filters in Georgia.

In making an award of punitive damages, you should consider the degree of reprehensibility of Bard's wrongdoing. You should consider all of the evidence, both aggravating and mitigating, to decide how much punishment, penalty, or deterrence Bard's conduct deserves in the form of punitive damages. In assessing reprehensibility, you may consider whether:

1) the harm caused was physical, as opposed to economic;

2) the conduct showed an indifference to or a reckless disregard of the health or safety of others; and

3) the conduct involved repeated actions or was an isolated incident.

You may have heard evidence of other conduct and procedures of Bard. For the purpose of punitive damages, you may not consider evidence of any conduct of Bard that

is dissimilar to that which resulted in Mrs. Jones' injury – unless such dissimilar conduct was related to the specific harm suffered by Mrs. Jones in this case.

Plaintiff's Objection:

Neither *State Farm* nor *Gore* limit damages to sales of a product in a particular state. Trial Tr. at 2587. Moreover, Georgia law relating to punitive damages specifically states that there shall be "no limitation" on the amount a jury can award for punitive damages. O.C.G.A. § 51-12-5.1. The concern expressed by the Supreme Court concerning out of state conduct is to ensure that it (1) is not legal in other states and (2) bears some relationship to the conduct at issue in the case. *State Farm*, 538 U.S. at 421-23.

Defendants' Response:

Defendants request these changes to the instruction given in *Booker* comply with the US Supreme Court decisions on punitive damages. *State Farm Mut. Auto. Ins. Co.* v. Campbell, 538 U.S. 408 (2003); BMW of N. Am., Inc. v. Gore, 517 U.S. 559 (1996); Dimaso v. Ford Motor Company, et. al., No. 99-A-6172-6, 2003 WL 22850075, at *1 (Ga. Super. 2003); *Hockensmith v. Ford Motor Co.,* No. 1:01-CV-3645G, 2003 WL 25639639, at *10 (N.D. Ga. Apr. 17, 2003). See also Georgia Suggested Pattern Jury Instructions, Vol. I: Civil Cases, No. 66.770-66.780 (5th ed. 2016).

Exhibit E

IN THE UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation, Doris Jones, an individual, Plaintiff, v. C. R. Bard, Inc., a New Jersey corporation; and Bard Peripheral Vascular, Inc., an Arizona corporation, Defendants.	No. MDL15-2641-PHX-DGC

COMPREHENSIVE FINAL JURY INSTRUCTIONS WITH COMPETING INSTRUCTIONS

DATED: May 1, 2018

David G. Campbell
United States District Judge

INSTRUCTION NO. 1

Members of the Jury: Now that you have heard all of the evidence, it is my duty to instruct you on the law that applies to this case.

A copy of these instructions will be sent to the jury room for you to consult during your deliberations.

It is your duty to find the facts from all the evidence in the case. To those facts you will apply the law as I give it to you. You must follow the law as I give it to you whether you agree with it or not. And you must not be influenced by any personal likes or dislikes, opinions, prejudices, or sympathy. That means that you must decide the case solely on the evidence before you. You will recall that you took an oath to do so.

Please do not read into these instructions or anything that I may say or do or have said or done as indicating that I have an opinion regarding the evidence or what your verdict should be.

Agreed

INSTRUCTION NO. 2

Although there are two defendants in this case, C.R. Bard, Inc. and Bard Peripheral Vascular, Inc., you should decide the case as to the two defendants jointly. As a result, in these instructions and in the verdict form, we will refer to defendants collectively as "Bard." Unless otherwise stated, the instructions apply to both Bard and Mrs. Jones.

Agreed

INSTRUCTION NO. 3

The evidence you are to consider in deciding what the facts are consists of:

1. the sworn testimony of the witnesses;

2. the exhibits that are admitted into evidence;

3. any facts to which the lawyers have agreed; and

4. any facts that I have instructed you to accept as proved.

Agreed

INSTRUCTION NO. 4

In reaching your verdict, you may consider only the testimony of the witnesses, the exhibits received into evidence, and facts to which the parties have agreed.

Certain things are not evidence, and you may not consider them in deciding what the facts are. I will list them for you:

1. Arguments and statements by lawyers are not evidence. The lawyers are not witnesses. What they have said in their opening statements, may say in closing arguments and at other times is intended to help you interpret the evidence, but it is not evidence. If the facts as you remember them differ from the way the lawyers have stated them, your memory of the facts controls.

2. Questions and objections by lawyers are not evidence. Attorneys have a duty to their clients to object when they believe a question is improper under the rules of evidence. You should not be influenced by the objection or by the court's ruling on it.

3. Testimony that is excluded or stricken, or that you were instructed to disregard, is not evidence and must not be considered. In addition some evidence is received only for a limited purpose; when I instruct you to consider certain evidence only for a limited purpose, you must do so and you may not consider that evidence for any other purpose.

4. Anything you may have seen or heard when the court was not in session is not evidence. You are to decide the case solely on the evidence received during the trial.

INSTRUCTION NO. 5

Some exhibits admitted into evidence have been partially "redacted," which means that certain contents of the exhibits have been blacked out or whited out. The parties and I have redacted information that is not properly admitted as evidence. You may give the unredacted information in any exhibit whatever weight you choose, but you must disregard the redacted information and must not speculate about what it might say.

Agreed

INSTRUCTION NO. 6

You have heard testimony from a number of witnesses who testified to opinions and the reasons for their opinions. This opinion testimony is allowed because of the education or experience of those witnesses.

Such opinion testimony should be judged like any other testimony. You may accept it or reject it, and give it as much weight as you think it deserves, considering the witness's education and experience, the reasons given for the opinion, and all the other evidence in the case.

Agreed

INSTRUCTION NO. 7

Federal law prohibits current FDA employees from testifying in court regarding any function of the FDA, and prohibits current and former FDA employees from testifying about information acquired in the discharge of their official duties, without authorization of the Commissioner of the FDA. As a result, neither side in this case was able to present testimony from current FDA employees or former FDA employees regarding the discharge of their duties related to this case.

Agreed

INSTRUCTION NO. 8

Certain charts and summaries not admitted into evidence have been shown to you in order to help explain the evidence in the case. These have been referred to as demonstrative exhibits. The demonstrative exhibits are only as good as the underlying evidence that supports them. You should, therefore, give them only such weight as you think the underlying evidence deserves.

Agreed

INSTRUCTION NO. 9

Certain charts and summaries have been admitted into evidence to illustrate information brought out in the trial. Charts and summaries are only as good as the testimony or other admitted evidence that supports them. You should, therefore, give these only such weight as you think the underlying evidence deserves.

Agreed

INSTRUCTION NO. 10.

All parties are equal before the law and a corporation is entitled to the same fair and conscientious consideration by you as any party.

Agreed

INSTRUCTION NO. 11

Under the law, a corporation is considered to be a person. It can only act through its employees, agents, directors, or officers. Therefore, a corporation is responsible for the acts of its employees, agents, directors, and officers performed within the scope of authority.

Agreed

INSTRUCTION NO. 12

Mrs. Jones asserts four claims against Bard: (1) Strict Product Liability Based on Design Defect; (2) Strict Product Liability Based on Failure to Warn; (3) Negligent Design; and (4) Negligent Failure to Warn. I will instruct you on the law that applies to each of these claims. You should consider each claim separately.

Agreed

INSTRUCTION NO. 13

Before I give you instructions about Mrs. Jones' specific claims, let me give you a few instructions that will apply to all of the claims.

When a party has the burden of proving any claim or affirmative defense by a "preponderance of the evidence," it means you must be persuaded by the evidence that the claim or affirmative defense is more probably true than not true. You should base your decision on all of the evidence, regardless of which party presented it.

Some instructions will state that you must find that an event or condition or action was the "proximate cause" of Mrs. Jones' injury. Proximate cause means that cause which, in a natural and continuous sequence, produces an event, and without which cause such event would not have occurred. Thus, when I use the expression "proximate cause," I mean a cause that, in the natural or ordinary course of events, produced Mrs. Jones' injury.

In order to be a proximate cause, the act or omission complained of must be such that a person using ordinary care would have foreseen that the event, or some similar event, might reasonably result.

There may be more than one proximate cause of an event. Thus, to prove proximate cause, Mrs. Jones need not prove that an act or omission was the only cause or the last or nearest cause. It is sufficient if it combines with another cause resulting in the injury. However, if an act or omission of any person not a party to the suit was the sole proximate cause of an occurrence, then no act or omission of any party could have been a proximate cause.

PLAINTIFF'S PROPOSED INSTRUCTION STRICT LIABILITY DESIGN

Mrs. Jones contends that Bard is strictly liable because of a defective design of the Eclipse IVC filter.

The manufacturer of a product that is sold as new property may be liable to any person who is injured because of a defect in the product that existed at the time the manufacturer sold the product. However, a manufacturer of a product is not an insurer, and the fact that a product may cause an injury does not necessarily make the manufacturer liable. To recover damages for strict product liability based on a design defect, Mrs. Jones must establish the following three elements by a preponderance of the evidence:

First, the product was defectively designed;

Second, the design defect existed at the time the product left the control of Bard; and

Third, the design defect in the product was a proximate cause of Mrs. Jones' injury.

There is not a single general way to define what constitutes a design defect in a product. Whether or not a product is defective is a question of fact to be determined by you, the jury, based on the instruction that I will give you and the evidence that has been received during the trial.

Although Bard is not required to ensure that a product design is incapable of producing injury, it has a duty to exercise reasonable care in choosing the design for a product.

To determine whether a product suffers from a design defect, you must balance the inherent risk of harm in a product design against the utility or benefits of that product design. You must decide whether the manufacturer acted reasonably in choosing a particular product design by considering all relevant evidence, including the following factors:

1) the usefulness of the product;

2) the severity of the danger posed by the design;

3) the likelihood of that danger;

4) the avoidability of the danger, considering the user's knowledge of the product, publicity surrounding the danger, the effectiveness of warnings, and common knowledge or the expectation of danger

5) the user's ability to avoid the danger;

6) the technology available when the product was manufactured;

7) the ability to eliminate the danger without impairing the product's usefulness or making it too expensive;

8) the feasibility of spreading any increased cost through the product's price;

9) the appearance and aesthetic attractiveness of the product;

10) the product's utility for multiple uses;

11) the convenience and durability of the product;

12) alternative designs of the product available to the manufacturer; and

13) the manufacturer's compliance with industry standards or government regulations.

In determining whether a product was defectively designed, you may consider evidence of alternative designs that would have made the product safer and could have prevented or minimized Mrs. Jones' injury. In determining the reasonableness of the product design chosen by Bard, you should consider:

1) the availability of an alternative design at the time Bard designed this product;

2) the level of safety from an alternative design compared to the actual design;

3) the feasibility of an alternative design, considering the market and technology at the time the product was designed;

4) the economic feasibility of an alternative design;

5) the effect an alternative design would have on the product's appearance and utility for multiple purposes; and

6) any adverse effects on Bard or the product from using an alternative design.

If you decide that the risk of harm in the product's design outweighs the utility of that particular design, then the manufacturer exposed the consumer to greater risk of danger than the manufacturer should have in using that product design, and the product is defective. If after balancing the risks and utility of the product, you find by a preponderance of the evidence that the product suffered from a design defect that proximately caused Mrs. Jones' injury, then Mrs. Jones is entitled to recover damages.

Defendants' Objections:

Bard objects to Plaintiff's proposed charge because she has deleted two necessary elements from this instruction as given in *Booker*. First, Plaintiff deleted the paragraph that refers to considering compliance with industry standards or government regulations, which is an element of the risk utility test set forth by the Georgia Supreme Court, and for which a separate jury instruction was created. See, Ga. Civil Pattern Instruction 62.670 below:

62.670 **Strict Liability; Design Defect; Compliance with Industry Standards or Government Regulations**

In determining whether a product was defective, you may consider proof of a manufacturer's compliance with federal or state safety standards or regulations and industrywide customs, practices, or design standards. Compliance with such standards or regulations is a factor to consider in deciding whether the product design selected was reasonable considering the feasible choices of which the manufacturer knew or should have known. However, a product may comply with such standards or regulations and still contain a design defect.

Banks v. ICI Americas Inc., 264 Ga. 732 (1994)

Doyle v. Volkswagenwerk Artiengesellschaft, 267 Ga. 574 (1997)

Second, Plaintiff also deleted the paragraph regarding regulatory action. However, under Georgia law when a plaintiff claims a design defect in a widely-distributed product, "[t]he fact that . . . [defendant] had never been subjected to regulatory action with respect to the claimed defect . . . tends to negate the allegation that the configuration was a dangerous design." *Browning v. Paccar, Inc.*, 214 Ga. App. 496, 498, 448 S.E.2d 260, 263 (1994). As such, "evidence that the customary methods for protecting the public from defective [products] had not been instituted in connection with these [products] was relevant to show defendant's design and manufacture was not negligent." *Id.*

Defendants' proposed alternative is Defendants' Instruction on Design Defect

Plaintiff's Response:

For the reasons stated in Booker, Bard's proposed language provides undue emphasis on FDA evidence, drawing the jury's attention to FDA actions and inactions on three separate occasions. This results in an emphasis or comment on certain types of evidence as more important than other factors.

DEFENDANTS' PROPOSED INSTRUCTION STRICT LIABILITY DESIGN

Mrs. Jones contends that Bard is strictly liable because of a defective design of the ECLIPSE IVC filter.

The manufacturer of a product that is sold as new property may be liable to any person who is injured because of a defect in the product that existed at the time the manufacturer sold the product. However, a manufacturer of a product is not an insurer, and the fact that a product may cause an injury does not necessarily make the manufacturer liable. To recover damages for strict product liability based on a design defect, Mrs. Jones must establish the following three elements by a preponderance of the evidence:

First, the product was defectively designed;

Second, the design defect existed at the time the product left the control of Bard; and

Third, the design defect in the product was a proximate cause of Mrs. Jones' injury.

There is not a single general way to define what constitutes a design defect in a product. Whether or not a product is defective is a question of fact to be determined by you, the jury, based on the instruction that I will give you and the evidence that has been received during the trial.

Although Bard is not required to ensure that a product design is incapable of producing injury, it has a duty to exercise reasonable care in choosing the design for a product.

To determine whether a product suffers from a design defect, you must balance the inherent risk of harm in a product design against the utility or benefits of that product design. You must decide whether the manufacturer acted reasonably in choosing a particular product design by considering all relevant evidence, including the following factors:

14) the usefulness of the product;

15) the severity of the danger posed by the design;

16) the likelihood of that danger;

17) the avoidability of the danger, considering the user's knowledge of the product, publicity surrounding the danger, the effectiveness of warnings, and common knowledge or the expectation of danger;

18) the user's ability to avoid the danger;

19) the technology available when the product was manufactured;

20) the ability to eliminate the danger without impairing the product's usefulness or making it too expensive;

21) the feasibility of spreading any increased cost through the product's price;

22) the appearance and aesthetic attractiveness of the product;

23) the product's utility for multiple uses;

24) the convenience and durability of the product;

25) alternative designs of the product available to the manufacturer; and

26) the manufacturer's compliance with industry standards or government regulations.

In determining whether a product was defectively designed, you may consider evidence of alternative designs that would have made the product safer and could have prevented or minimized Mrs. Jones' injury. In determining the reasonableness of the product design chosen by Bard, you should consider:

1) the availability of an alternative design at the time Bard designed this product;

2) the level of safety from an alternative design compared to the actual design;

3) the feasibility of an alternative design, considering the market and technology at the time the product was designed;

4) the economic feasibility of an alternative design;

5) the effect an alternative design would have on the product's appearance and utility for multiple purposes; and

6) any adverse effects on Bard or the product from using an alternative design.

In determining whether a product was defective, you may consider proof of a manufacturer's compliance with federal or state safety and non-safety standards or regulations and industrywide customs, practices, or design standards. Compliance with such standards or regulations is a factor to consider in deciding whether the product design selected was reasonable considering the feasible choices of which the manufacturer knew or should have known. However, a product may comply with such standards or regulations and still contain a design defect.

In deciding whether the design of the ECLIPSE filter was defective, you may also consider whether the FDA instituted regulatory action with respect to the ECLIPSE filter. However, a product may be defective even if the FDA institutes no regulatory action.

If you decide that the risk of harm in the product's design outweighs the utility of that particular design, then the manufacturer exposed the consumer to greater risk of danger than the manufacturer should have in using that product design, and the product is defective. If after balancing the risks and utility of the product, you find by a preponderance of the evidence that the product suffered from a design defect that proximately caused Mrs. Jones' injury, then Mrs. Jones is entitled to recover.

Plaintiff's Objection:

The instruction places undue emphasis on FDA evidence, focusing the jury's attention on FDA action or inaction on three separate occasions.

Defendants' Response:

This is the instruction given in *Booker* with only the name and product name changed. As is stated in Defendants' objection to Plaintiff's proposed instruction, Plaintiff deleted two necessary elements from the instruction, the Georgia Pattern Instruction on compliance with industry standards and the language reflecting Georgia law regarding regulatory action. Defendants incorporate their objection to Plaintiff's proposed instruction on strict liability design.

STRICT LIABILITY FAILURE TO WARN

Mrs. Jones contends that Bard is strictly liable because it failed to give adequate warnings regarding the Eclipse IVC filter.

The manufacturer of a product that is sold as new property may be liable to any person who is injured because of an inadequate warning with respect to the product that existed at the time the manufacturer sold the product. However, a manufacturer of a product is not an insurer, and the fact that a product may cause an injury does not necessarily make the manufacturer liable.

The manufacturer of a medical device does not have a duty to warn the patient of the dangers involved with the product, but instead has a duty to warn the patient's doctor, who acts as a learned intermediary between the patient and the manufacturer.

To recover damages for strict liability based on an inadequate warning, Mrs. Jones must establish the following three elements by a preponderance of the evidence:

First, the warning given with the product was inadequate;

Second, the inadequate warning existed at the time the product left the control of Bard; and

Third, the inadequate warning was a proximate cause of Mrs. Jones' injury.

There is no single general way to define what constitutes an inadequate warning in a product. Whether or not a warning is inadequate is a question of fact to be determined by you, the jury, based on the instruction that I will give you and the evidence received during the trial.

Bard had a duty to give an adequate warning of known or reasonably foreseeable dangers arising from the use of its Eclipse IVC filter. Bard owes this duty to warn to all physicians whom the manufacturer should reasonably foresee may use the product. Bard's duty to warn may have been breached by:

a) failing to provide an adequate warning of the Eclipse filter's potential dangers or

b) failing to adequately communicate to Mrs. Jones' physicians the warning provided.

A manufacturer's duty to warn arises when the manufacturer knows or reasonably should know of the danger presented by the use of the product. Therefore, a manufacturer

has a continuing duty to adequately warn of defects in a product even after that product has left the control of the manufacturer.

You must decide whether adequate efforts were made by Bard to communicate all risks that were known or reasonably should have been known to Bard, to the physician who implanted the Eclipse filter in Mrs. Jones, and whether the warning that Bard communicated was adequate.

A product, however well or carefully made, that is sold without an adequate warning of such danger, may be said to be in a defective condition. If you find by a preponderance of the evidence that Bard did not adequately warn when an adequate warning should have been given, and that this inadequate warning proximately caused Mrs. Jones' injury, then you may find the Eclipse filter to be defective and for that reason, find that Mrs. Jones is entitled to recover damages.

PLAINTIFF'S PROPOSED INSTRUCTION NEGLIGENT DESIGN

Mrs. Jones claims that Bard was negligent in the design of the Eclipse IVC filter she received. To recover on this claim, Mrs. Jones must prove by a preponderance of the evidence that:

(1) Bard had a duty of reasonable care to Mrs. Jones,

(2) Bard breached that duty in the design of the Eclipse filter,

(3) the breach was a proximate cause of Mrs. Jones' injury, and

(4) she suffered damages.

Reasonable care is that degree of care that is used by ordinarily careful manufacturers under the same or similar circumstances.

If Mrs. Jones has failed to prove any one of the four elements by a preponderance of the evidence, then you must find that Bard was not negligent in the design of the Eclipse filter she received.

Defendants' Objections:

Defendants acknowledge that Plaintiff's proposed instruction is the same as the one given in *Booker*. However, Defendants object to this this instruction on the grounds that it does not comply with Georgia law. See, *Ogletree v. Navistar International Transportation Corporation*, 271 Ga. 644 (1999), in which the Georgia Supreme Court held, "In a negligent design case, the risk-utility analysis applies to determine whether the manufacturer is liable. Thus, the mandate that a product's risk must be weighed against its utility incorporates the concept of 'reasonableness' so as to apply negligence principles in the determination of whether the manufacturer defectively designed its product." (Citations omitted)

Defendants' proposed alternative is Defendants' Proposed Instruction on negligent design.

Plaintiff's Response:

Plaintiff believes the instruction given in Booker was appropriate and avoids undue comment on the evidence of risk-benefit, which is but one of many factors a jury may consider in examining the evidence.

DEFENDANTS' PROPOSED INSTRUCTION NEGLIGENT DESIGN

Mrs. Jones claims that Bard was negligent in the design of the ECLIPSE IVC filter she received. To recover on this claim, Mrs. Jones must prove by a preponderance of the evidence that:

(1) Bard had a duty of reasonable care to Mrs. Jones,

(2) Bard breached that duty in the design of the ECLIPSE filter,

(3) the breach was a proximate cause of Mrs. Jones' injury, and

(4) she suffered damages.

Reasonable care is that degree of care that is used by ordinarily careful manufacturers under the same or similar circumstances. In making the determination of whether Bard acted reasonably, you should consider the risk-benefit analysis for design defect about which I previously instructed you.

If Mrs. Jones has failed to prove any one of the four elements by a preponderance of the evidence, then you must find that Bard was not negligent in the design of the ECLIPSE filter she received.

Plaintiff's Objection:

Plaintiff proposes that the instruction from Booker be given, with name and product information modified. Bard's proposed language would confuse the negligent design instruction with the strict product liability instruction making risk/benefit a de facto element of both claims and unnecessarily emphasizing this aspect of the claim.

Defendants' Response:

Defendants request that this language be added to make the instruction consistent with Georgia law. See, *Ogletree v. Navistar International Transportation Corporation*, 271 Ga. 644 (1999), in which the Georgia Supreme Court held, "In a negligent design case, the risk-utility analysis applies to determine whether the manufacturer is liable. Thus, the mandate that a product's risk must be weighed against its utility incorporates the concept of "reasonableness" so as to apply negligence principles in the determination of whether the manufacturer defectively designed its product. (Citations omitted)"

PLAINTIFF'S PROPOSED INSTRUCTION NEGLIGENT FAILURE TO WARN

Mrs. Jones claims that Bard was negligent in failing to warn about the risks of the Eclipse IVC filter she received. To recover on this claim, Mrs. Jones must prove by a preponderance of the evidence that:

(1) Bard had a duty of reasonable care to Mrs. Jones (via warnings to her physicians),

(2) Bard breached that duty in the adequacy of the warnings about the Eclipse filter,

(3) the breach was a proximate cause of the her injury, and

(4) she suffered damages.

A medical device manufacturer has a duty to warn physicians of a danger arising from use of a product once that danger becomes known to the manufacturer. Therefore, a manufacturer has a continuing duty to adequately warn of defects in a product even after that product has left the control of the manufacturer.

Reasonable care is the degree of care that is used by ordinarily careful manufacturers under the same or similar circumstances.

If Mrs. Jones has failed to prove any one of the four elements by a preponderance of the evidence, then you must find that Bard was not negligent in failing to warn about the risks of the Eclipse filter she received.

Source: Ga. Code Ann., § 51-1-11(C); Ford Motor Co. v. Reese, 684 S.E.2d 279, 284 (Ga. App. 2009).

Defendants' Objections:

Defendants object to this instruction as it is not a proper statement under Georgia law. Under Georgia law, whether premised on negligence or strict liability, Plaintiff must prove that "Bard had a duty to give an adequate warning of known or reasonably foreseeable dangers arising from the use of its filter. *Shelton v. GALCO Int'l, Ltd.*, No. 3:16-CV-00033-TCB, 2017 WL 3597497 (N.D. Ga. July 19, 2017) (quoting *Chrysler Corp. v. Batten*, 450 S.E.2d 208, 211 (Ga. 1994)) ("[T]he duty to warn arises whenever the manufacturer knows or reasonably should know of the danger arising from the use of the product."). Further, Plaintiff's reliance on *Battersby v. Boyer*, 526 S.E.2d 159, 162 (Ga. Ct. App. 1999) is misplaced. While the Georgia Courts acknowledge that there are

two separate causes of action, they also recognize that the same duty based elements apply to both strict liability and negligent failure to warn. J. Kennard Neal and Catherine Payne, *Ga. Products Liability Law* § 8:1 (4th ed. 2018) ("Georgia has traditionally recognized failure to warn claims arising both in negligence and in strict liability. [H]owever, Georgia courts make no distinction between the two, but apply the same duty concepts and the same tripartite test of foreseeability.") (citations omitted); *Id.* at § 2:1 ("[I]n examining either type of claim, Georgia courts have consistently applied the same duty-based negligence analysis.")

As to the duty owed to the physician, Defendants request that the same language used in the strict liability failure to warn be included.

Defendants' proposed alternative is Defendants' Proposed Instruction on negligent failure to warn.

Plaintiff's Response:

Plaintiff does not agree to Bard's proposed merger of the negligent failure to warn with the strict liability failure to warn instruction. Such theories of liability are separate and distinct, thus making the Booker instruction appropriate. *Battersby v. Boyer*, 526 S.E.2d 159, 162 (Ga. Ct. App. 1999).

DEFENDANTS' PROPOSED INSTRUCTION NEGLIGENT FAILURE TO WARN

Mrs. Jones claims that Bard was negligent in failing to warn Dr. Avino about the risks of the ECLIPSE IVC filter he implanted in Ms. Jones. To recover on this claim, Mrs. Jones must prove by a preponderance of the evidence that:

(1) Bard had a duty of reasonable care to Mrs. Jones,

(2) Bard breached that duty in the adequacy of the warnings about the ECLIPSE filter provided to Dr. Avino,

(3) the breach was a proximate cause of the her injury, and

(4) she suffered damages.

Reasonable care is that degree of care that is used by ordinarily careful manufacturers under the same or similar circumstances. In making the determination of whether Bard acted reasonably in warning Dr. Avino, you should consider the same factors for strict liability failure to warn about which I previously instructed you.

The manufacturer of a medical device does not have a duty to warn the patient of the dangers involved with the product, but instead has a duty to warn the patient's doctor, who acts as a learned intermediary between the patient and the manufacturer.

If Mrs. Jones has failed to prove any one of the four elements by a preponderance of the evidence, then you must find that Bard was not negligent in failing to warn about the risks of the ECLIPSE filter she received.

Plaintiff's Objection:

Plaintiff objects only to the highlighted text. The proposed reference back to the strict liability instruction will be confusing to the jury since it would send the message that it is deciding the same issue for both claims when such claims are separate and distinct. *Battersby v. Boyer*, 526 S.E.2d 159, 162 (Ga. Ct. App. 1999).

Defendant's Response:

Defendants request these revisions to the instruction given in *Booker* to comply with Georgia law. Under Georgia law, whether premised on negligence or strict liability, Plaintiff must prove that "Bard had a duty to give an adequate warning of known or reasonably foreseeable dangers arising from the use of its filter. *Shelton v. GALCO Int'l*,

Ltd., No. 3:16-CV-00033-TCB, 2017 WL 3597497 (N.D. Ga. July 19, 2017) (quoting *Chrysler Corp. v. Batten*, 450 S.E.2d 208, 211 (Ga. 1994)) ("[T]he duty to warn arises whenever the manufacturer knows or reasonably should know of the danger arising from the use of the product."). Further, Plaintiff's reliance on *Battersby v. Boyer*, 526 S.E.2d 159, 162 (Ga. Ct. App. 1999) is misplaced. While the Georgia Courts acknowledge that there are two separate causes of action, they also recognize that the same duty based elements apply to both strict liability and negligent failure to warn. J. Kennard Neal and Catherine Payne, *Ga. Products Liability Law* § 8:1 (4th ed. 2018) ("Georgia has traditionally recognized failure to warn claims arising both in negligence and in strict liability. [H]owever, Georgia courts make no distinction between the two, but apply the same duty concepts and the same tripartite test of foreseeability.") (citations omitted); *Id.* at § 2:1 ("[I]n examining either type of claim, Georgia courts have consistently applied the same duty-based negligence analysis.")

Also, and importantly, the instruction as previously written is confusing because it refers to a duty to the "Plaintiff," but in the context of a medical device the duty is to the implanting physician. *McCombs v. Synthes*, 277 Ga. 252, 253, 587 S.E.2d 594 (2003). If learned intermediary is not included in both the strict liability and negligent failure to warn instructions, Defendants request that it be given as a separate instruction as set forth below.

LEARNED INTERMEDIARY

The manufacturer of a medical device does not have a duty to warn the patient of the dangers involved with the product, but instead has a duty to warn the patient's doctor, who acts as a learned intermediary between the patient and the manufacturer.

McCombs v. Synthes, 277 Ga. 252, 253, 587 S.E.2d 594 (2003)

PLAINTIFF'S PROPOSED INSTRUCTION RE MANUFACTURER'S SCOPE OF KNOWLEDGE

PRODUCTS LIABILITY – DEFECT DUE TO INADEQUATE WARNING; MANUFACTURER HELD TO THE KNOWLEDGE AND SKILL OF AN EXPERT

In cases such as the instant case, a manufacturer is held to the knowledge and skill of an expert. This is relevant in determining (1) whether the manufacturer knew or should have known of a danger in its product and (2) whether the manufacturer was negligent in failing to communicate this superior knowledge. The manufacturer's status as an expert means that at a minimum, it must keep abreast of scientific knowledge, discoveries, and advances and is presumed to know what is imported thereby.

Even more importantly, a manufacturer has a duty to test and inspect its product. The extent of research and experiment must be commensurate with the dangers involved. A product must not be made available without disclosures of these dangers that the application of reasonable foresight would reveal. Nor, may a manufacturer rely unquestioningly on others to sound such disclosure concerning a danger in this product. Rather, each manufacturer must bear the burden of showing that its own conduct was proportionate to the scope of its duty.

Borel v. Fibreboard Paper Prods., Corp., 493 F 2d 1076, 1080-1090 (5th Circuit);
The Corporation of Mercer University v. National Gypsum Co., et al., 1986 WL 12445 (M.D. Ga. 1986).

Defendants' Objections:

Defendants object to this instruction on the grounds that it is not a proper statement of Georgia law. The cases cited by Plaintiff do not apply to this case. *Borel v. Fibreboard Paper Prods, Corp*. 493 F. 2d 1076 (1973) applies Texas law. Plaintiff cites no case that stands for this proposition under Georgia law. In addition, *The Corporation of Mercer University v. National Gypsum Co*, 1986 WL 12445 (M.D. Ga. 1986) is not applicable. It was a property damage claim over the removal of asbestos and does not stand for the proposition stated in the charge. The charge expands the duty of a manufacturer beyond what is required by Georgia law. The Court refused to give this instruction in *Booker*.

Defendants propose as alternative instruction their proposed instructions on strict liability and negligent failure to warn.

Plaintiff's Response:

The law is correctly stated as set forth in *Mercer, supra*. While Mercer was an asbestos case, it stands for the unremarkable and unsurprising proposition that

manufacturers of products should, at a minimum, be aware of the knowledge available in the scientific community concerning their products. *Id.* at *2.

PLAINTIFF'S PROPOSED INSTRUCTION RE SCOPE OF DUTY TO WARN

PRODUCTS LIABILITY – MANUFACTURER'S DUTY TO WARN

You must decide whether adequate efforts were made by Bard to communicate all risks that were known to Bard or reasonably should have been known to Bard to the physician who implanted the Eclipse Filter in Mrs. Jones, and whether the warning that Bard communicated was adequate. A warning is inadequate if it does not provide a complete disclosure of both the existence of the risk and the extent of the danger and the severity of any potential injury involved.

Chrysler Corp. v. Batten, 264 Ga. 723, 724 (1994);
Ford Motor Co. v. Stubblefield, 171 Ga. App. 331, 335 (1984);
Watkins v. Ford Motor Co., 190 F. 3d 1213, 1220 (11th Cir. 1999);
Stapleton v. Kawasaki Heavy Indus., Inc., 608 F.2d 571, 573 (5th Cir. 1979);
White v. W.G.M. Safety Corp., 707 F. Supp. 544, 549 (S.D. Ga. 1988);
Bryant v. Hoffman-La Roche, Inc., 262 Ga. App. 401, 410 (2003);
Sands v. Kawasaki Motors Corp., 2009 WL 3152859, at *5 (S.D. Ga. Sept. 30, 2009).

Defendants' Objections:

Defendants object to this instruction on the grounds that it is not a proper statement of Georgia law and attempts to extend the duty to warn beyond what is required. It is also duplicative of the instruction on failure to warn and will confuse the jury. Further in a case involving a learned intermediary, the fact the risks were known in the medical community is a factor that should be considered by the jury. *See Wheat v. Sofamor, S.N.C.*, 46 F.Supp.2d 1351, 1363 (N.D.Ga.1999) and *Ellis. C.R. Bard, Inc.*, 311 F.3d 1272 (2002). The Court declined to give this instruction in *Booker.*

Defendants propose as alternative instructions their proposed instructions on strict liability and negligent failure to warn. If the Court is inclined to give this instruction in addition to those, Defendants propose as an alternative instruction:

You must decide whether adequate efforts were made by Bard to communicate the risks that were known to Bard or reasonably should have been known to Bard to the physician who implanted the Eclipse Filter in Ms. Jones, and whether the warning that Bard communicated was adequate. However, in making that determination you make take into account whether the risks were generally known by Dr. Avino and the medical community generally.

Plaintiff's Response:

The proposed instruction correctly states the law and simply advises the jury that a warning that is inadequate if it does not fully disclose the risks and the extent of the danger. Plaintiff does not object to a modification of the instruction to clarify that the warning must be to physicians, not patients, but believes this topic is adequately covered in other instructions.

PLAINTIFF'S PROPOSED INSTRUCTION RE RISKS TO BE WARNED ABOUT

PRODUCTS LIABILITY – DUTY TO WARN OF KNOWN DANGERS AND DANGERS THAT SHOULD HAVE BEEN KNOWN

In considering whether Bard violated its duty to warn, you may consider not only what dangers Bard knew at the time the product was sold, but also what Bard should have known at that time by the application of reasonable, developed human skill.

Bishop v. Farhat, 227 Ga. App. 201, 206 (1997).

Defendants' Objections:

Defendants object to this instruction on the grounds that it is duplicative of the proposed instructions on strict liability and negligent failure to warn. This charge is a paraphrase from *Bishop v. Farhat*, which actually cites to *Chrysler Corp. v Batten*, 264 Ga. 723 (1994). The Georgia Pattern Instruction on strict liability failure to warn is likewise taken from *Batten*. Therefore, there is no need for an additional charge.

Plaintiff's Response:

This instruction is helpful to the jury in understanding the contours of the failure to warn claim and merely instructs (accurately) on the law imposing the duty to warn on Bard.

DEFENDANTS' REQUEST FOR INSTRUCTION
FAILURE TO READ WARNING

If a physician does not actually read a warning provided by the manufacturer of a medical device, the adequacy or lack of adequacy of that warning cannot be the proximate cause of the plaintiff's injuries.

Plaintiff's Objection:

This instruction is unnecessary and improper. Questions of causation are for the jury. In addition, Bard had a continuing duty to warn of dangers under Georgia law. Issuance of post-implantation warnings could have allowed for retrieval of Mrs. Jones' filter before it fractured. Ga. Code Ann., Section 51-1-11(C). Further, the instruction is an improper comment on the evidence. It also will be confusing since Dr. Avino testified that he read the IFUs for Bard devices and, even if a jury assumes they are predecessor devices, the warnings are the same for the Eclipse IFU.

Defendants' Response:

Under Georgia law, the failure to warn claim can be based on either the adequacy of the warning or the adequacy of the attempts to communicate the warning. Failure to read a warning prevents recovery on the first part of the claim. "[F]ailure to read instructions or printed warnings will prevent a plaintiff from recovering on a claim grounded on failure to provide adequate warning of the product's potential risk." *Wilson Foods Corp. v. Turner*, 218 Ga. App. 74, 75, 460 S.E.2d 532, 534 (1995); *Camden Oil Co., LLC v. Jackson*, 609 S.E.2d 356, 358 (Ga. App. 2004) ("where a plaintiff does not read an allegedly inadequate warning, the adequacy of the warning's contents cannot be a proximate cause of the plaintiff's injuries"). The evidence in the case is that the Eclipse IFU contains different (and contained additional) warnings than the predecessor devices.

ASSUMPTION OF RISK

Bard asserts an "assumption of the risk" defense. If Mrs. Jones knew of the Eclipse IVC filter's defect and was aware of the danger, but nevertheless proceeded unreasonably to make use of the product, taking a risk which in and of itself amounts to a failure to exercise ordinary care for her safety, she cannot later hold Bard responsible for any injury suffered due to taking such a risk.

To establish the defense of assumption of the risk, Bard must prove by a preponderance of the evidence that:

1) Mrs. Jones knew of the danger posed by the Eclipse IVC filter,

2) Mrs. Jones understood and appreciated the risks of that product, and

3) Mrs. Jones knowingly and voluntarily exposed herself to such a risk.

If you find that Bard has proved each of these elements by a preponderance of the evidence, then Mrs. Jones is not entitled to recover for the resulting injury or damages, and you should return a verdict for Bard.

Agreed

PLAINTIFF'S REQUESTED FDA LIMITING INSTRUCTION

The FDA's review of a medical device depends upon how the device is classified under FDA regulations.

Certain devices are reviewed under FDA's Pre-Market Approval (PMA) process, which approves products focusing on a device's "safety and efficacy."

The FDA's 510(k) process determines whether a device is "substantially equivalent" to another device already legally on the market., it does not evaluate devices for safety and efficacy.

Bard's IVC filters, including Doris Jones' Eclipse IVC filter, were not FDA approved through the PMA process, but were cleared by the FDA through its 510(k) process.

Defendants' Objections:

Defendants object to this instruction on the grounds that it is a comment on facts that should be testified to by witnesses or presented through exhibits. Defendants do not offer an alternative instruction as they do not believe that a statement on the facts or evidence is appropriate

Plaintiff's Response:

Plaintiff responds that this instruction is likely to be appropriate given the emphasis at trial on FDA activity with respect to filter clearance. In submitting this instruction, Plaintiff understands that the Court will evaluate the evidence at trial to determine whether such an instruction is necessary.

DEFENDANTS' REQUEST FOR INSTRUCTION
JURY DELIBERATION; PRODUCT DEFECT

If you find by a preponderance of the evidence that the product was defective in design or the adequacy of the warning provided when it left the control of the manufacturer and that the plaintiff's injury was proximately caused by that defect, then you would return a verdict for the plaintiff, unless the plaintiff is denied recovery under some other principle of law given to you in these charges.

If after considering all the evidence, you do not believe by a preponderance of the evidence that the product by which plaintiff claims to have been injured was defective in design or adequacy of the warning when it left the manufacturer's control or that the product was the proximate cause of the plaintiff's injury, then you would end your deliberations; the plaintiff would not be entitled to recover; and you would return a verdict for the defendant.

Georgia Pattern Instruction 62.720 Jury Deliberation; Product Defect

Plaintiff's Objection:

This instruction is unnecessary in light of other final instructions given to the jury. In addition, it is confusing and risks having the jury believe that it must find for Plaintiff on all claims to render a verdict (or both design or both warning claims). There are *four* separate claims and a jury need only find for Plaintiff on *one* of these claims. This instruction muddles that fact.

Defendants' Response:

This is a Georgia pattern instruction that is not encompassed in the instructions as given and provides the jury with necessary guidance on how to proceed during their deliberations.

DAMAGES

It is the duty of the court to instruct you about the measure of damages. By instructing you on damages, I do not mean to suggest for which party your verdict should be rendered.

If you find for Mrs. Jones on any or all of her claims, you must determine her damages. Mrs. Jones has the burden of proving damages by a preponderance of the evidence. It is for you to determine what damages, if any, have been proved. Your award must be based on evidence and not on speculation, guesswork or conjecture.

Damages are given as pay or compensation for injury done. Where one party is required to pay damages to another, the law seeks to ensure that the damages awarded are fair to both parties. If you find by a preponderance of the evidence that Mrs. Jones is entitled to recover damages, you should award to Mrs. Jones such sums as you believe are reasonable and just in this case.

Necessary expenses resulting from the injury are a legitimate item of damages. As to medical expenses, such as hospital, doctor, and medicine bills, the amount of the damage would be the reasonable value of such expense as was reasonably necessary.

Mrs. Jones seeks to recover not only for her past medical expenses, but also for medical expenses that may be incurred in the future. If you find that the evidence shows with reasonable certainty that Mrs. Jones will sustain future medical expenses proximately caused by the actions of Bard, and if you find that the evidence shows with reasonable certainty the amount of such future medical expenses, Mrs. Jones would be entitled to recover those amounts, reduced to present cash value.

Pain and suffering are recoverable as damages. The measure of damages for pain and suffering is left to the enlightened conscience of fair and impartial jurors. Questions of whether, how much, and how long Mrs. Jones has suffered or will suffer are for you to decide.

Pain and suffering include mental suffering, but mental suffering is not recoverable as damages unless there is also physical suffering. In evaluating Mrs. Jones' pain and suffering, you may consider the following factors, if proven:

(1) interference with normal living;

(2) interference with enjoyment of life;

(3) impairment of bodily health and vigor;

(4) fear of extent of injury;

(5) shock of impact;

(6) actual pain and suffering, past and future;

(7) mental anguish, past and future; and

(8) the extent to which Mrs. Jones must limit activities.

If you find that Mrs. Jones' pain and suffering will continue into the future, you should award such damages for future pain and suffering as you believe Mrs. Jones will endure. In making such an award, your standard should be your enlightened conscience as impartial jurors. You may take into consideration the fact that Mrs. Jones is receiving a present cash value award for damages not yet suffered.

Bard must take Mrs. Jones in whatever condition it finds her. A negligent actor must bear the risk that its liability will be increased by reason of the actual physical condition of the person toward whom its act is negligent. Thus, if you find that Mrs. Jones' injuries were increased by her existing physical condition, you may award damages for those increased injuries provided you find they were proximately caused by Bard.

Defendants' Objection:

Defendants object to the last paragraph as it is not conformed to the evidence in this case. There is no evidence or testimony that any actions of Bard caused or contributed to Ms. Jones' existing medical conditions.

Plaintiff's Response:

To the extent Bard is allowed to introduce evidence of Plaintiff's unrelated medical conditions or allegedly acting against medical advice, the limiting paragraph is important to clarify for the jury that the defendant takes the victim as it finds her. If Plaintiff's MIL Nos. 1-3 are granted, Plaintiff will agree to withdraw the last paragraph.

DEFENDANTS' PROPOSED INSTRUCTION DAMAGES

It is the duty of the court to instruct you about the measure of damages. By instructing you on damages, I do not mean to suggest for which party your verdict should be rendered.

If you find for Mrs. Jones on any or all of her claims, you must determine her damages. Mrs. Jones has the burden of proving damages by a preponderance of the evidence. It is for you to determine what damages, if any, have been proved. Your award must be based on evidence and not on speculation, guesswork or conjecture.

Damages are given as pay or compensation for injury done. Where one party is required to pay damages to another, the law seeks to ensure that the damages awarded are fair to both parties. If you find by a preponderance of the evidence that Mrs. Jones is entitled to recover damages, you should award to Mrs. Jones such sums as you believe are reasonable and just in this case.

Necessary expenses resulting from the injury are a legitimate item of damages. As to medical expenses, such as hospital, doctor, and medicine bills, the amount of the damage would be the reasonable value of such expense as was reasonably necessary.

Mrs. Jones seeks to recover not only for her past medical expenses, but also for medical expenses that may be incurred in the future. If you find that the evidence shows with reasonable certainty that Mrs. Jones will sustain future medical expenses proximately caused by the actions of Bard, and if you find that the evidence shows with reasonable certainty the amount of such future medical expenses, Mrs. Jones would be entitled to recover those amounts, reduced to present cash value.

Pain and suffering are recoverable as damages. The measure of damages for pain and suffering is left to the enlightened conscience of fair and impartial jurors. Questions of whether, how much, and how long Mrs. Jones has suffered or will suffer are for you to decide.

Pain and suffering include mental suffering, but mental suffering is not recoverable as damages unless there is also physical suffering. In evaluating Mrs. Jones' pain and suffering, you may consider the following factors, if proven:

(1) interference with normal living;

(2) interference with enjoyment of life;

(3) impairment of bodily health and vigor;

(4) fear of extent of injury;

(5) shock of impact;

(6) actual pain and suffering, past and future;

(7) mental anguish, past and future; and

(8) the extent to which Mrs. Jones must limit activities.

If you find that Mrs. Jones' pain and suffering will continue into the future, you should award such damages for future pain and suffering as you believe Mrs. Jones will endure. In making such an award, your standard should be your enlightened conscience as impartial jurors. You may take into consideration the fact that Mrs. Jones is receiving a present cash value award for damages not yet suffered.

Plaintiff's Objection:

This instruction omits an important paragraph advising the jury that Bard must take the Plaintiff as it finds her and is not relieved of liability by virtue of any pre-existing conditions Plaintiff has. The Booker instruction adequately addresses this situation and merely sets forth a correct statement of the law.

Defendants' Response:

Defendants deleted and object to the last paragraph of the instruction given in *Booker* as not conformed to the evidence in this case. There is no evidence or testimony that any actions of Bard caused or contributed to Ms. Jones' existing medical conditions.

DEFENDANTS' REQUEST FOR INSTRUCTION
TORT DAMAGES; DUTY TO LESSEN

When a person is injured by the negligence of another, she must mitigate her damages as much as is practicable by the use of ordinary care and diligence.

If you find that plaintiff has suffered damages as alleged, under the law, she is bound to reduce those damages, as much as is practicable, by the use of ordinary care. If you believe that by the use of such care that she could have reduced the damages, you would determine to what extent and reduce such damages to that extent.

Georgia Pattern Instruction 66.015 Tort Damages; Duty to Lessen

Plaintiff's Objection:

There is no evidence supporting Mrs. Jones' alleged failure to mitigate her damages. Thus, instructing the jury on this issue will be confusing and contrary to the evidence. See also Plaintiff MILs 1-3.

Defendants' Response:

Plaintiff claims several alleged injuries for which she has received medical care and instruction that she has failed to follow. To the extent that she attributes those to the filter, her failure to follow medical advice or seek medical attention is relevant. O.C.G.A. §51-12-11*; Mallock v. Kicklighter*, 10 Ga. App. 605 (1912).

PUNITIVE DAMAGES

In cases such as this, there may be aggravating circumstances that warrant the award of additional damages called punitive damages. Punitive damages are intended to punish, penalize, and deter wrongful conduct.

Before you may award punitive damages, Mrs. Jones must prove that the actions of Bard showed willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care that would raise the presumption of conscious indifference to consequences.

Mrs. Jones must make this proof by clear and convincing evidence. This is a different and higher burden of proof than a preponderance of the evidence, but is less than the standard of "beyond a reasonable doubt," which is the proof required in criminal cases. Clear and convincing evidence is defined as evidence that will cause you to firmly believe, to a high degree of probability, that the requirements for punitive damages have been proved.

If Mrs. Jones fails to prove by clear and convincing evidence that Bard was guilty of willful misconduct, malice, fraud, wantonness, oppression, or entire want of care that would raise the presumption of conscious indifference to consequences, then you may not award punitive damages. Mere negligence, even amounting to gross negligence, will not alone authorize an award of punitive damages.

In the verdict form, you will be asked to specify whether Mrs. Jones is entitled to recover punitive damages, but you will not yet be asked to determine an amount of punitive damages. If you decide that she should be awarded punitive damages, then you will receive some brief additional instructions, evidence, and argument before setting the amount.

There can be no recovery of punitive damages in this case unless there is first a recovery by Mrs. Jones of compensatory damages.

PROCESS OF DELIBERATIONS

Before you begin your deliberations, please elect one member of the jury as your presiding juror. The presiding juror will preside over the deliberations and serve as the spokesperson for the jury in court.

You shall diligently strive to reach agreement with all of the other jurors if you can do so. Your verdict must be unanimous.

Each of you must decide the case for yourself, but you should do so only after you have considered all of the evidence, discussed it fully with the other jurors, and listened to their views.

It is important that you attempt to reach a unanimous verdict but, of course, only if each of you can do so after having made your own conscientious decision. Do not be unwilling to change your opinion if the discussion persuades you that you should. But do not come to a decision simply because other jurors think it is right, or change an honest belief about the weight and effect of the evidence simply to reach a verdict.

INSTRUCTIONS FOR DELIBERATIVE PROCESS

Because you must base your verdict only on the evidence received in the case and on these instructions, I remind you that you must not be exposed to any other information about the case or to the issues it involves. Except for discussing the case with your fellow jurors during your deliberations:

> Do not communicate with anyone in any way and do not let anyone else communicate with you in any way about the merits of the case or anything to do with it. This includes discussing the case in person, in writing, by phone or electronic means, via email, via text messaging, or any internet chat room, blog, website or application, including but not limited to Facebook, YouTube, Twitter, Instagram, LinkedIn, Snapchat, or any other forms of social media. This applies to communicating with your family members, your employer, the media or press, and the people involved in the trial. If you are asked or approached in any way about your jury service or anything about this case, you must respond that you have been ordered not to discuss the matter and to report the contact to the court.
>
> Do not read, watch, or listen to any news or media accounts or commentary about the case or anything to do with it; do not do any research, such as consulting dictionaries, searching the Internet, or using other reference materials; and do not make any investigation or in any other way try to learn about the case on your own. Do not visit or view any place discussed in this case, and do not use Internet programs or other devices to search for or view any place discussed during the trial. Also, do not do any research about this case, the law, or the people involved – including the parties, the witnesses or the lawyers – until you have been excused as jurors. If you happen to read or hear anything touching on this case in the media, turn away and report it to me as soon as possible.

As I've explained before, these rules protect each party's right to have this case decided only on evidence that has been presented here in court. Witnesses here in court take an oath to tell the truth, and the accuracy of their testimony is tested through the trial process. If you do any research or investigation outside the courtroom, or gain any information through improper communications, then your verdict may be influenced by inaccurate, incomplete or misleading information that has not been tested by the trial process. Each of the parties is entitled to a fair trial by an impartial jury, and if you decide the case based on information not presented in court, you will have denied the parties a fair trial. Remember, you have taken an oath to follow the rules, and it is very important that you follow these rules.

A juror who violates these restrictions jeopardizes the fairness of these proceedings, and a mistrial could result that would require the entire trial process to start over. If any juror is exposed to any outside information, please notify the court immediately.

Agreed

VIEWING EXHIBITS

The exhibits received in evidence that are capable of being displayed electronically will be provided to you in that form, and you will be able to view them in the jury room. A computer, projector, printer and accessory equipment will be available to you in the jury room.

A court technician will show you how to operate the computer and other equipment; how to locate and view the exhibits on the computer; and how to print the exhibits. You will also be provided with a paper list of all exhibits received in evidence. You may request a paper copy of any exhibit received in evidence by sending a note through the bailiff. If you need additional equipment or supplies or if you have questions about how to operate the computer or other equipment, you may send a note to the bailiff, signed by your presiding juror or by one or more members of the jury. Do not refer to or discuss any exhibit you were attempting to view.

If a technical problem or question requires hands-on maintenance or instruction, a court technician may enter the jury room with the bailiff present for the sole purpose of assuring that the only matter that is discussed is the technical problem. When the court technician or any non-juror is in the jury room, the jury shall not deliberate. No juror may say anything to the court technician or any non-juror other than to describe the technical problem or to seek information about operation of the equipment. Do not discuss any exhibit or any aspect of the case.

The sole purpose of providing the computer in the jury room is to enable you to view the exhibits received in evidence in this case. You may not use the computer for any other purpose. At my direction, technicians have taken steps to ensure that the computer does not permit access to the Internet or to any "outside" website, database, directory, game, or other material. Do not attempt to alter the computer to obtain access to such materials. If you discover that the computer provides or allows access to such materials, you must inform the court immediately and refrain from viewing such materials. Do not remove the computer or any electronic data from the jury room, and do not copy any such data.

COMMUNICATION WITH THE COURT

If it becomes necessary during your deliberations to communicate with me, you may send a note through the bailiff, signed by any one or more of you. No member of the jury should ever attempt to communicate with me except by a signed writing. I will not communicate with any member of the jury on anything concerning the case except in writing or here in open court with the parties present. If you send out a question, I will consult with the lawyers before answering it, which may take some time. You may continue your deliberations while waiting for the answer to any question. Please remember that you are not to tell anyone – including the court – how the jury stands, whether in terms of vote count or otherwise, until after you have reached a unanimous verdict or have been discharged. Do not disclose any vote count in any note you may send out to the Court.

Agreed

VERDICT FORMS

A verdict form has been prepared for you. [*Explain verdict form as needed.*] After you have reached unanimous agreement on a verdict, your foreperson should complete the verdict form according to your deliberations, sign and date it, and advise the bailiff that you are ready to return to the courtroom.

PLAINTIFF'S PROPOSED INSTRUCTION RE PUNITIVE DAMAGES

Members of the jury, you have decided that Mrs. Jones should be awarded punitive damages. In order to determine the amount of punitive damages, the parties have presented evidence and will now present brief arguments.

The measure of punitive damages is your enlightened conscience as an impartial jury. Any award you make should be both reasonable and just in light of your previous award of compensatory damages, the conduct and circumstances of Bard, and the purpose of punitive damages.

In considering the amount of punitive damages, you may consider the following factors:

1) the nature and reprehensibility of Bard's conduct;

2) the extent and duration of Bard's wrongdoing and the likelihood of its recurrence;

3) the intent of Bard in committing the wrong;

4) the profitability of Bard's wrongdoing;

5) the amount of compensatory damages you have previously awarded;

6) the financial circumstances, that is, the financial condition or the net worth of Bard.

In making an award of punitive damages, you should consider the degree of reprehensibility of Bard's wrongdoing. You should consider all of the evidence, both aggravating and mitigating, to decide how much punishment, penalty, or deterrence Bard's conduct deserves in the form of punitive damages. In assessing reprehensibility, you may consider whether:

1) the harm caused was physical, as opposed to economic;

2) the conduct showed an indifference to or a reckless disregard of the health or safety of others; and

3) the conduct involved repeated actions or was an isolated incident.

You may have heard evidence of other conduct and procedures of Bard. For the purpose of punitive damages, you may not consider evidence of any conduct of Bard that

is dissimilar to that which resulted in Mrs. Jones' injury – unless such dissimilar conduct was related to the specific harm suffered by Mrs. Jones in this case.

Defendants' Objections:

Defendants acknowledge that Plaintiff's proposed instruction is the same as the one that was given in *Booker*; however, Defendants object to this charge because it does not comply with the US Supreme Court decisions on punitive damages. See, State *Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408 (2003); *BMW of N. Am., Inc. v. Gore*, 517 U.S. 559 (1996); *Dimaso v. Ford Motor Company, et. al.*, No. 99-A-6172-6, 2003 WL 22850075, at *1 (Ga. Super. 2003); *Hockensmith v. Ford Motor Co.*, No. 1:01-CV-3645G, 2003 WL 25639639, at *10 (N.D. Ga. Apr. 17, 2003). See also Georgia Suggested Pattern Jury Instructions, Vol. I: Civil Cases, No. 66.770-66.780 (5th ed. 2016).

Defendants' proposed alternative is Defendants' Proposed Instruction A regarding punitive damages.

Plaintiff's Response:

For the reasons stated in Plaintiff's response to Bard's new charge on punitive damages, Plaintiff maintains that the Booker instruction accurately stated the law and is appropriate for this case.

DEFENDANTS' PROPOSED INSTRUCTION A – PUNITIVE DAMAGES

Members of the jury, you have decided that Mrs. Jones should be awarded punitive damages. In order to determine the amount of punitive damages, the parties have presented evidence and will now present brief arguments.

The measure of punitive damages is your enlightened conscience as an impartial jury. Any award you make should be both reasonable and just in light of your previous award of compensatory damages, the conduct and circumstances of Bard, and the purpose of punitive damages.

In considering the amount of punitive damages, you may consider the following factors:

1) the nature and reprehensibility of Bard's conduct;

2) the extent and duration of Bard's wrongdoing and the likelihood of its recurrence;

3) the intent of Bard in committing the wrong;

4) the profitability of Bard's wrongdoing in Georgia;

5) the amount of compensatory damages you have previously awarded;

6) the financial circumstances, that is, the financial condition or the net worth of Bard based on the sale of Eclipse filters in Georgia.

In making an award of punitive damages, you should consider the degree of reprehensibility of Bard's wrongdoing. You should consider all of the evidence, both aggravating and mitigating, to decide how much punishment, penalty, or deterrence Bard's conduct deserves in the form of punitive damages. In assessing reprehensibility, you may consider whether:

1) the harm caused was physical, as opposed to economic;

2) the conduct showed an indifference to or a reckless disregard of the health or safety of others; and

3) the conduct involved repeated actions or was an isolated incident.

You may have heard evidence of other conduct and procedures of Bard. For the purpose of punitive damages, you may not consider evidence of any conduct of Bard that

is dissimilar to that which resulted in Mrs. Jones' injury – unless such dissimilar conduct was related to the specific harm suffered by Mrs. Jones in this case.

Plaintiff's Objection:

Neither *State Farm* nor *Gore* limit damages to sales of a product in a particular state. Trial Tr. at 2587. Moreover, Georgia law relating to punitive damages specifically states that there shall be "no limitation" on the amount a jury can award for punitive damages. O.C.G.A. § 51-12-5.1. The concern expressed by the Supreme Court concerning out of state conduct is to ensure that it (1) is not legal in other states and (2) bears some relationship to the conduct at issue in the case. *State Farm*, 538 U.S. at 421-23.

Defendants' Response:

Defendants request these changes to the instruction given in *Booker* comply with the US Supreme Court decisions on punitive damages. *State Farm Mut. Auto. Ins. Co.* v. Campbell, 538 U.S. 408 (2003); BMW of N. Am., Inc. v. Gore, 517 U.S. 559 (1996); Dimaso v. Ford Motor Company, et. al., No. 99-A-6172-6, 2003 WL 22850075, at *1 (Ga. Super. 2003); *Hockensmith v. Ford Motor Co.,* No. 1:01-CV-3645G, 2003 WL 25639639, at *10 (N.D. Ga. Apr. 17, 2003). See also Georgia Suggested Pattern Jury Instructions, Vol. I: Civil Cases, No. 66.770-66.780 (5th ed. 2016).

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation

MDL NO. 15-02641-PHX-DGC

This Document Relates to:

DORIS JONES,

Plaintiff,

v.

Case No. CV-16-00782-PHX-DGC

C. R. BARD, INC., a New Jersey Corporation; AND BARD PERIPHERAL VASCULAR INC., an Arizona Corporation,

Defendants.

DEFENDANTS' PROPOSED FORM

In accordance with the Case Management Order No. 28 [Doc. 8871], Defendants hereby submit their proposed Verdict Form.

DATED this 1st day of May, 2018.

s/Richard B. North, Jr.
Richard B. North, Jr.
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Attorney for Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on May 1, 2018, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system which will send notification of such filing to all counsel of record.

s/Richard B. North, Jr.
Richard B. North, Jr.
Georgia Bar No. 545599
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We, the jury empaneled and sworn in the above action, upon our oaths, find as follows:

A. LIABILITY

1. Strict Product Liability Design Defect Claim

Do you find by a preponderance of the evidence that Bard is liable to Ms. Jones on the strict liability design defect claim? _____Yes _____No

2. Strict Product Liability Failure to Warn Claim

Do you find by a preponderance of the evidence that Bard is liable to Ms. Jones on the strict liability failure to warn claim? _____Yes _____No

3. Negligent Design Claim

Do you find by a preponderance of the evidence that Bard is liable to Ms. Jones on the negligent design claim? _____Yes _____No

4. Negligent Failure to Warn Claim

Do you find by a preponderance of the evidence that Bard is liable to Ms. Jones on the negligent failure to warn claim? _____Yes _____No

If you answered "No" to each question in Part A, do not complete Parts B or C. If you answered "Yes" to any question in Part A, please complete Parts B and C.

B. COMPENSATORY DAMAGES

If you found Bard liable on any of the claims set forth above, what amount of damages do you find will reasonably compensate Ms. Jones for her injuries?

$ _____

C. PUNITIVE DAMAGES

Do you find by clear and convincing evidence that punitive damages should be awarded against Bard? _____Yes _____No

_____ _____

Presiding Juror Number Date

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EXHIBIT E
(Filed Under Seal)

EXHIBIT F

New York Methodist Hospital

Patient Name: BOOKER, SHERR UNA [redacted] 000100496723 MRN: 00004260066

Diagnostic Radiology

EXAM DATE/TIME	ACCESSION	PROCEDURE	ORDERING PROVIDER
6/21/2007 12:38 EDT	01-XR-07-044926	XR Fluoro in the Operating Room	D'ayala MD,Marcus

Reason For Exam
(XR Fluoro in the Operating Room) pvd

Read
Fluoroscopy Stucy dated 6/21/07.

Clinical history: IVC filter placement.

Fluoroscopy was performed in the operating room and fluoroscopic spot films of lumbar region were obtained during the placement of the IVC filter through femoral approach with contrast seen in the IVC to identify the level for deploying the IVC filter which is seen at the level of L2-L3 vertebra.

Impression

IVC filter placement at the level of L2-L3 vertebra.

*** FINAL ***

Dictated By: Pinnapureddy MD , Perashuram

Electronically Signed By: Pinnapureddy MD , Perashuram
06/26/2007 15:35

EXHIBIT G

From: Ciavarella, David [/O=BARD/OU=MHL AG/CN=RECIPIENTS/CN=DCIAVARELLA]
Date: 12/27/2005 2:33:22 PM
To: Barry, Brian [Brian.Barry@crbard.com], Ganser, Christopher [Christopher.Ganser@crbard.com]
Subject: FW: G2 Caudal Migrations

My comments to Cindi and Gin.

_____

From: Ciavarella, David
Sent: Friday, December 23, 2005 2:32 PM
To: Walcott, Cindi
Cc: Allen, Shari; Schulz, Gin
Subject: RE: G2 Caudal Migrations

Thank you Cindi.

I think we should discuss these further so I can get a better understanding of each one. But first, it would help if I had a little more information.

From what you've sent me, it seems to me that the biggest (worst case) consequence of these migrations is that they are accompanied in a majority of cases by tilting. This raises the concern of lack of efficacy, that is, are the filters now in place to perform clot interruption? I would guess not in several of these cases at least.

I would like to look more generally at the G2 complaints. I have seen problems with caudal migration, tilting, perforation, mis-deployment and maybe one or two additional things. Can you tell me the total number of complaints (not damaged packages and the like) and total number of units distributed?

How many MDRs have we had for G2?

The G2 is a permanent filter; we also have one (the SNF) that has virtually no complaints associated with it. Why shouldn't doctors be using that one rather than the G2? Can you also send me the total complaints rate and MDR complaint rate for SNF?

I'll be in the office next Tues and Wed; maybe we can talk one of those days.

David

_____

From: Walcott, Cindi
Sent: Tue 12/20/2005 6:14 PM
To: Ciavarella, David
Cc: Allen, Shari; Schulz, Gin
Subject: G2 Caudal Migrations

David,

During a conference call with the design team of the G2 filter and Chris Ganser today, the caudal migrations of the G2 were briefly discussed.

Chris asked if I had submitted any MDRs on these events yet and I answered yes. Chris asked me to review the events with you to determine what events have the potential for serious injury and establish a baseline for the future. Presently, based on the description of the events and the history of a filter being removed, I have coded them all as reportable. Please note that I cut the descriptions straight out of what was entered into Trackwise. I can see that some of the descriptions are a bit rough.

Please see the attachment, which has a description of the events to date.

1. Record 63855- I submitted that one as an MDR because there was also a report of perforation with this patient. Perforations have caused serious injuries with previous filters. We have always reported perforations of the Recovery Filter and the Simon Nitinol filters. The doctor also removed the filter due to the perforation and migration.
2. Record 65220- I submitted this one as an MDR, as the filter migrated into the renal veins and caused the patient flank pain.
3. Record 65851- I reported this one as it migrated 3cm and is currently at the iliac confluence.

Thanks for your assistance,

Cindi

EXHIBIT H
(Filed Under Seal)

EXHIBIT I
(Filed Under Seal)

EXHIBIT J

Filters
Complaint History
Data as of 7/31/07

Natalie Wong

Privileged and Confidential

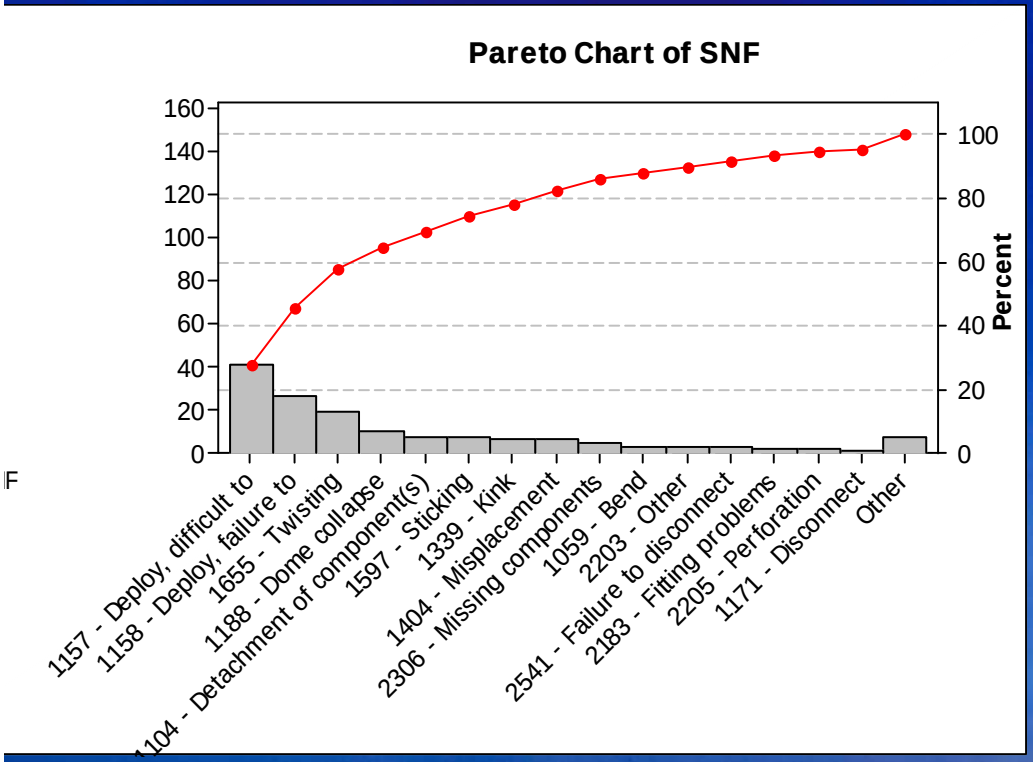
Simon Nitinol Filter

Product Codes: 2120F, 2220J, 2320A

Complaint History

Data as of 7/31/07

SNF Complaints by FDA Device Code



FDA Device Code	Last Update (4/30/07)	New (6/30/07)	Total
1157 - Deploy, difficult to	41	0	41
1158 - Deploy, failure to	25	1	26
1655 - Twisting	18	1	19
1188 - Dome collapse	10	0	10
1104 - Detachment of component(s)	7	0	7
1597 - Sticking	7	0	7
1339 - Kink	6	0	6
2306 - Missing components	5	0	5
1404 - Misplacement	4	2	6
2541 - Failure to disconnect	3	0	3
1059 - Bend	2	1	3
2203 - Other	2	1	3
2183 - Fitting problems	2	0	2
2205 - Perforation	2	0	2
1171 - Disconnect	1	0	1
1243 - Filter, assembly	1	0	1
1259 - Foreign material	1	0	1
1316 - Difficult to insert	1	0	1
1395 - Migration	1	0	1
2312 - Incomplete/missing packaging	1	0	1
2594 - Sharp/jagged/rough/etched/scratched	1	0	1
2204 - Unknown	1	0	1
Total	**142**	**6**	**148**

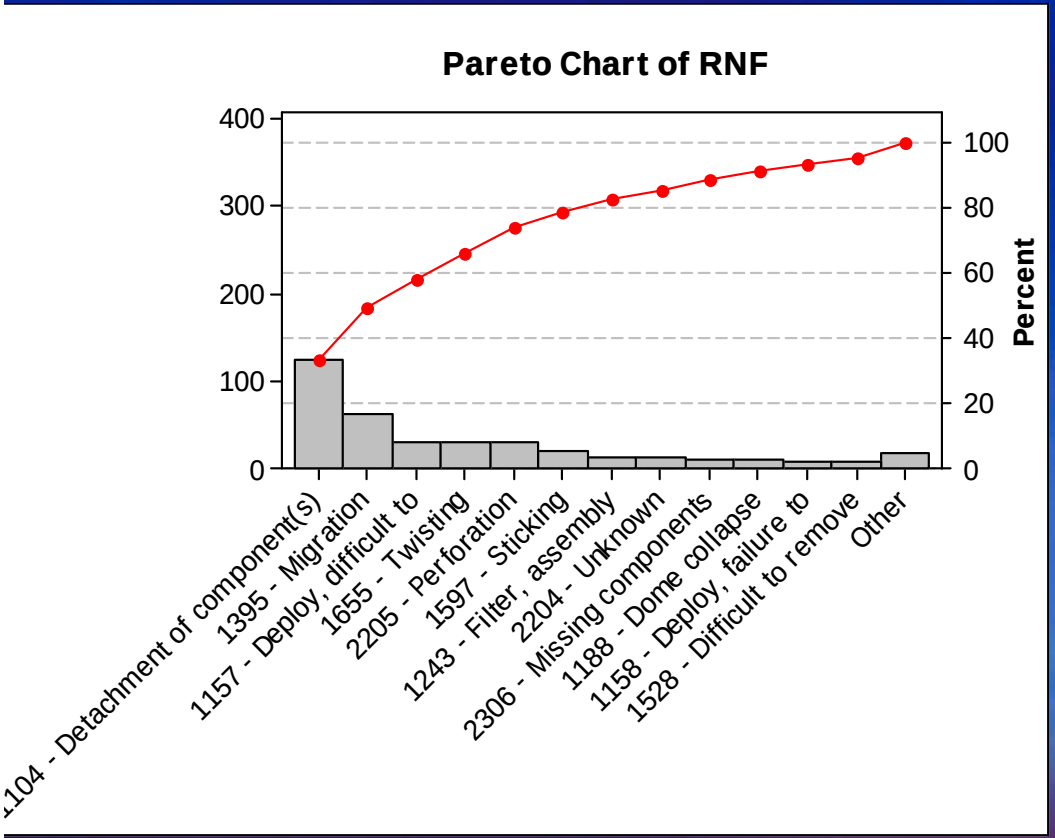
Recovery Filter (Gen 1)

Product Code: RF048F

Complaint History

Data as of 7/31/07

Recovery Complaints by FDA Device Code



FDA Device Code	Last Update (4/30/07)	New (7/31/07)	Total
1104 - Detachment of component(s)	118	5	123
1395 - Migration	61	0	61
1157 - Deploy, difficult to	31	0	31
1655 - Twisting	31	0	31
2205 - Perforation	29	0	29
1597 - Sticking	19	0	19
1243 - Filter, assembly	13	0	13
2204 - Unknown	12	0	12
2306 - Missing components	11	0	11
1188 - Dome collapse	10	0	10
1158 - Deploy, failure to	8	0	8
1528 - Difficult to remove	8	0	8
1404 - Misplacement	3	0	3
2320 - Removal of implant	3	0	3
1059 - Bend	2	0	2
1081 - Failure to capture	1	0	1
1316 - Difficult to insert	1	0	1
1339 - Kink	1	0	1
1423 - Occlusion	1	0	1
1628 - Holes, rips, tears in device, device material	1	0	1
2183 - Fitting problems	1	0	1
2203 - Other	1	0	1
2311 - Out-of-box failure	1	0	1
2594 - Sharp/jagged/rough/etched/scratched	1	0	1
Total	**368**	**5**	**373**

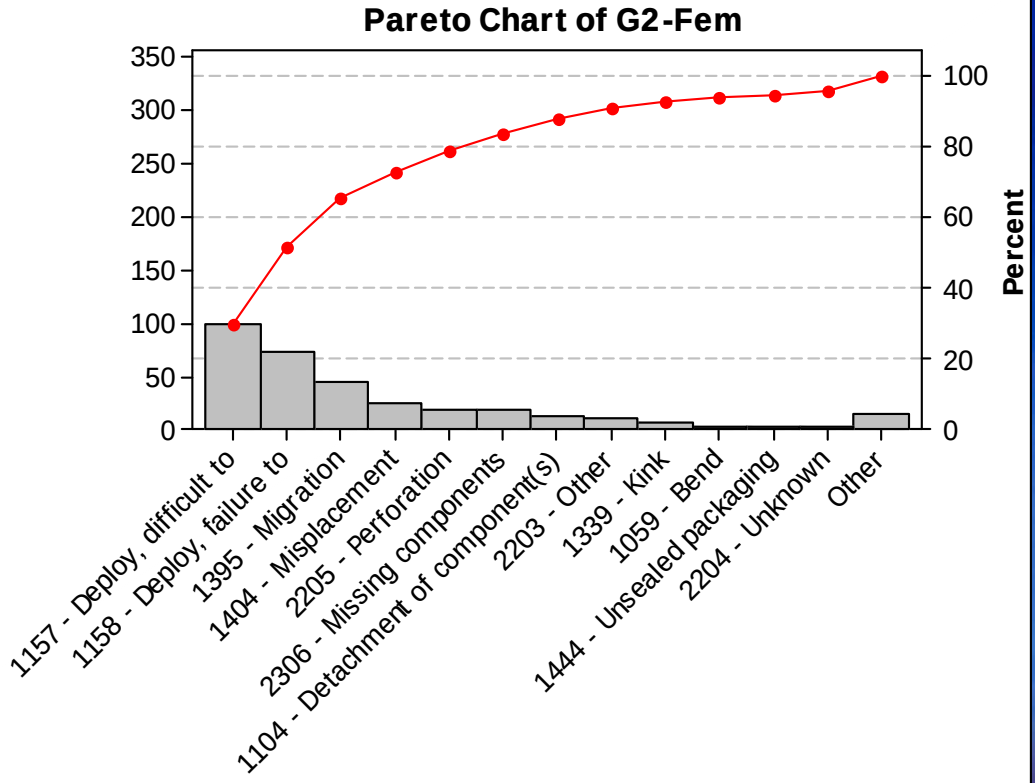
G2 Filter – Femoral Delivery

Product Codes: RF310F, RF210F

Complaint History

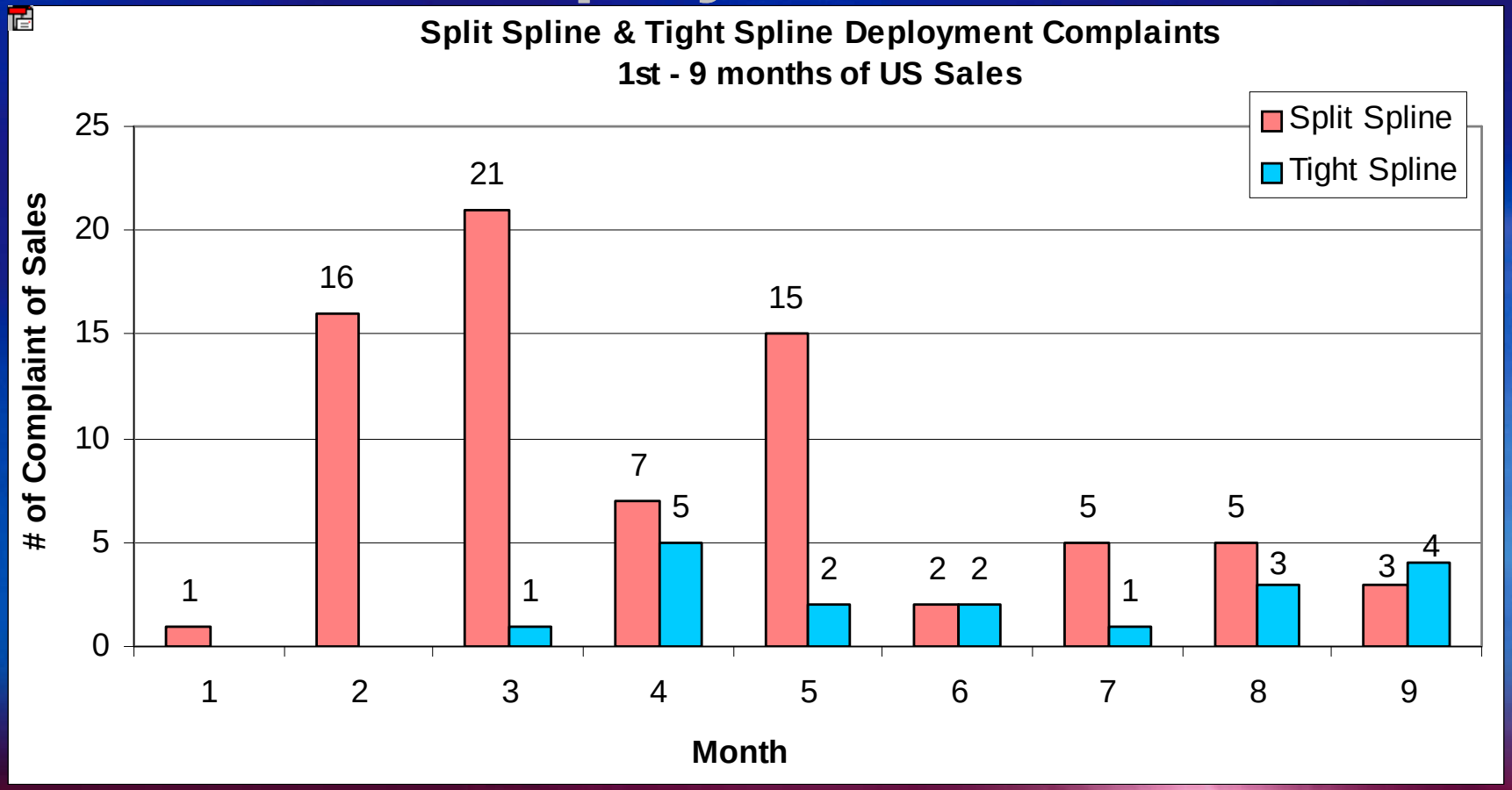
Data as of 7/31/07

G2 Complaints by FDA Device Code



FDA Device Code	Last Update (4/30/07)	New (7/31/07)	Total
1157 - Deploy, difficult to	91	8	99
1158 - Deploy, failure to	66	7	73
1395 - Migration	43	2	45
- Cephalad	(8)	(0)	
- Caudal	(35)	(2)	
1404 - Misplacement	25	0	25
2306 - Missing components	16	2	18
2205 - Perforation	15	4	19
1104 - Detachment of component(s)	12	1	13
2203 - Other	10	1	11
1059 - Bend	3	0	3
2204 - Unknown	3	0	3
1339 - Kink	2	4	6
1444 - Unsealed packaging	2	1	3
1316 - Difficult to insert	1	1	2
1655 - Twisting	2	0	2
1423 - Occlusion	1	1	2
1528 - Difficult to remove	1	1	2
2311 - Out-of-box failure	1	1	2
1108 - Incompatible component(s)	1	0	1
1188 - Dome collapse	1	0	1
1454 - Peeling	1	0	1
1484 - Premature deployment	1	0	1
Total	**298**	**34**	**332**

G2 Femoral Deployment Issues



Cumulative Rates
Split Spline = 0.59%
Tight Spline* = 0.11%

***Tight Spline data is thru 7/31/07**

Unit Sales Sold during this Period
Split Spline = 12,675
Tight Spline = 15,772

G2 Femoral Deployment Issues

Split Spline		Tight Spline		Unknown*
1st 9 Months of US Sales	# Split Spline Complaints	1st 9 Months of US Sales	# Tight Spline Complaints	# Unknown* Complaints
Sep-05	1	Nov-06	0	0
Oct-05	16	Dec-06	0	1
Nov-05	21	Jan-07	1	4
Dec-05	7	Feb-07	5	3
Jan-06	15	Mar-07	2	2
Feb-06	2	Apr-07	2	2
Mar-06	5	May-07	1	1
Apr-06	5	Jun-07	3	0
May-06	3	Jul-07	4	4
TOTAL	**75**		**18**	**17**
Unit Sales	**12,675**		**15,772**	**Unknown***
Complaint Rate	**0.59%**		**0.11%**	-

*# Unknown complaints are complaints where the lot number is unknown or the sample was not returned. These unknown complaints are since the release of Tight Spline (11/22/06 thru 7/31/07).

First 9 Months of US Sales:

Split Spline: 75 complaints

Tight Spline: 18 complaints

Tight Spline + Unknown (Worst Case) = 35 complaints

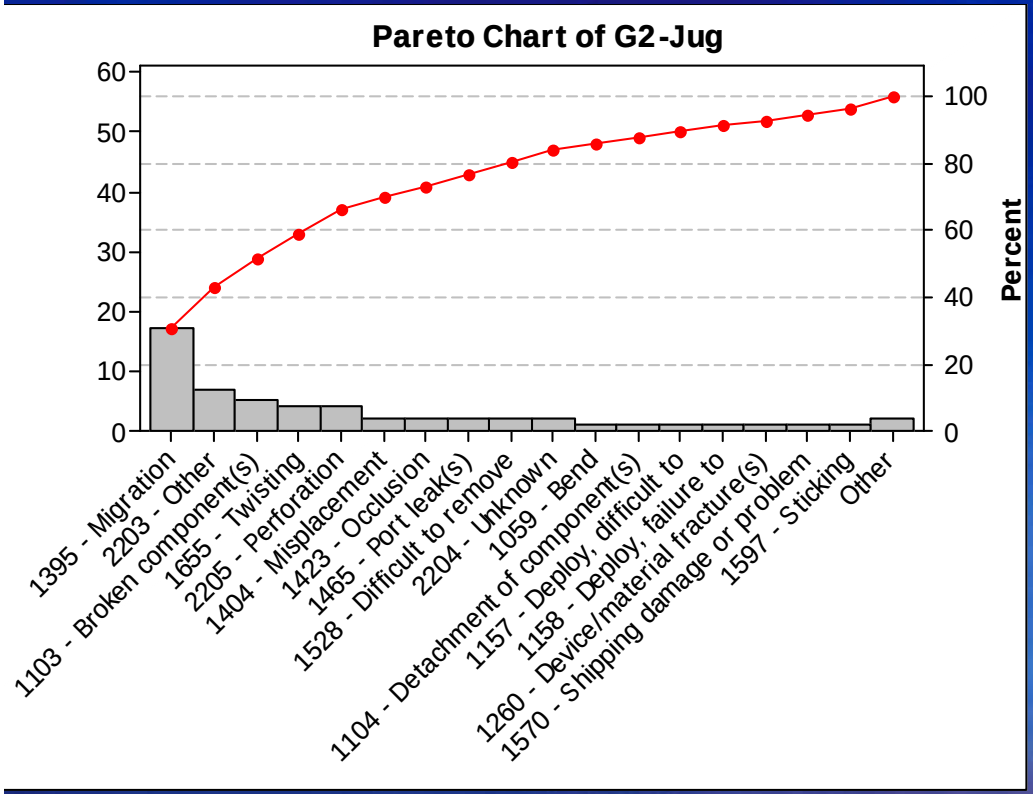
G2 Filter – Jugular Delivery

Product Codes: RF320J, RF220J

Complaint History

Data as of 7/31/07

G2 Complaints by FDA Device Code



FDA Device Code	Last Update (4/30/07)	New (7/31/07)	Total
1395 - Migration	15	2	17
- Cephalad	(0)	(0)	
- Caudal	(15)	(2)	
2203 - Other	5	2	7
1103 - Broken component(s)	5	0	5
1655 - Twisting	3	1	4
2205 - Perforation	2	2	4
1404 - Misplacement	2	0	2
1423 - Occlusion	2	0	2
1465 - Port leak(s)	2	0	2
1528 - Difficult to remove	2	0	2
2204 - Unknown	2	0	2
1104 - Detachment of component(s)	1	0	1
1157 - Deploy, difficult to	1	0	1
1158 - Deploy, failure to	1	0	1
1260 - Device/material fracture(s)	1	0	1
1570 - Shipping damage or problem	1	0	1
1597 - Sticking	1	0	1
2306 - Missing components	1	0	1
1059 - Bend	0	1	1
2409 - Malfunction	0	1	1
Total	**47**	**9**	**56**

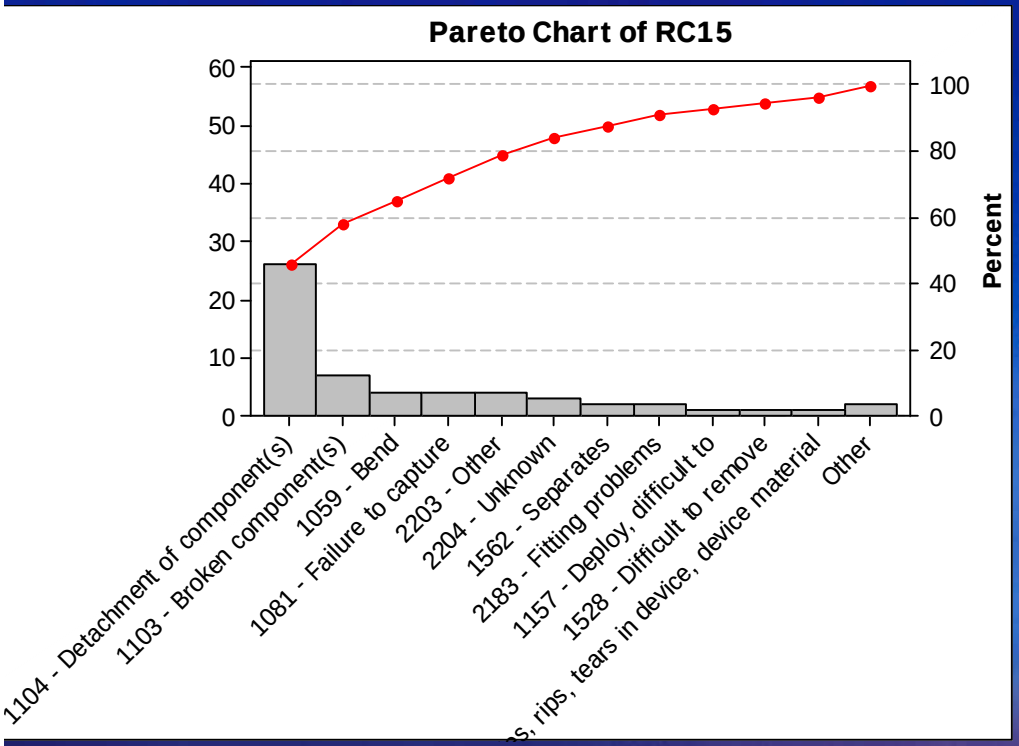
Recovery Cone

Product Codes: RC15

Complaint History

Data as of 7/31/07

Recovery Cone Complaints by FDA Device Code



FDA Device Code	Last Update (4/30/07)	New (7/31/07)	Total
1104 - Detachment of component(s)	25	1	26
1103 - Broken component(s)	5	2	7
1059 - Bend	4	0	4
1081 - Failure to capture	4	0	4
2203 - Other	3	1	4
2204 - Unknown	3	0	3
1562 - Separates	2	0	2
2183 - Fitting problems	2	0	2
1157 - Deploy, difficult to	1	0	1
1528 - Difficult to remove	1	0	1
1628 - Holes, rips, tears in device, device material	1	0	1
1655 - Twisting	1	0	1
2306 - Missing components	1	0	1
Total	**53**	**4**	**57**

BARD PERIPHERAL VASCULAR

Recovery and G2 Complaints vs. SIR Guidelines

Data as of 7/31/07

Recovery and G2 Compared to SIR Guidelines

Potential Complications	Complication/Trackable Event Rates from SIR Guidelines (all filters)[1]	Threshold % from SIR Guidelines (all filters)[2]	Recovery Filter No. of Events (n)	Recovery Filter Complaint Rate (%)	G2 Filter No. of Events (n)	G2 Filter Complaint Rate[4] (%)
Units Sold	-	-	32,344		49,692	
Cephalad Movement/Migration (2cm+)[3]	0-18%	2%	57	0.176%	8	0.016%
Caudal Movement/Migration (2cm+)[3]			6	0.019%	54	0.109%
Filter Fracture	2-10%	Not Reported	129	0.399%	14	0.028%
Perforation	0-41%	Not Reported	35	0.108%	41	0.083%
Pulmonary Embolism	0.5-6%	5%	10	0.031%	5	0.010%
Caval Thrombosis / Occlusion	2-30%	10%	4	0.012%	4	0.008%
Extravasations of Contrast at time of Cava Gram	Not Reported	Not Reported	1	0.003%	0	0.000%
Death (includes all events list above)	0.12%	<1%	18	0.056%	2	0.004%
Tilt	Not Reported	Not Reported	19	0.059%	54	0.109%

[1]Grassi CJ, Swan TL, Cardella JF, et al. Quality Improvement Guidelines for Percutaneous Permanent Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism.

[2]Suggested threshold for individual practices for purposes of case review.

[3]Migration/Movement includes filter embolization as described in Grassi, above.

[4]G2 Sales reported through 7/31/07

Recovery and G2 Event Data is through 7/31/07

BARD PERIPHERAL VASCULAR

MAUDE – Competitor Complaint vs. SIR Guidelines

Data as of 6/30/07

SIR vs. Vena Tech and Greenfield

Potential Complications	Complication/Trackable Event Rates from SIR Guidelines (all filters)[1]	Threshold % from SIR Guidelines (all filters)[2]	Vena Tech (P) No. of Events (n)	Vena Tech (P) Complaint Rate[4] (%)	Greenfield (P) No. of Events (n)	Greenfield (P) Complaint Rate[4] (%)
Units Sold	-	-	79,738		225,340	
Cephalad Movement/Migration (2cm+)[3]	0-18%	2%	30	0.038%	53	0.024%
Caudal Movement/Migration (2cm+)[3]			0	0.000%	0	0.000%
Filter Fracture	2-10%	Not Reported	1	0.001%	9	0.004%
Perforation	0-41%	Not Reported	0	0.000%	12	0.005%
Pulmonary Embolism	0.5-6%	5%	1	0.001%	4	0.002%
Caval Thrombosis / Occlusion	2-30%	10%	0	0.000%	1	0.000%
Extravasations of Contrast at time of Cava Gram	Not Reported	Not Reported	Not Reported	-	Not Reported	-
Death (includes all events list above)	0.12%	<1%	5	0.006%	5	0.002%
Tilt	Not Reported	Not Reported	0	0.000%	0	0.000%

[1]Grassi CJ, Swan TL, Cardella JF, et al. Quality Improvement Guidelines for Percutaneous Permanent Inferior Vena Cava Filter Placement for the Prevention of
[2]Suggested threshold for individual practices for purposes of case review.
[3]Migration/Movement includes filter embolization as described in Grassi, above.
[4]Competitor Sales data from IMS Q1 2007

(P) = Permanent Filter
(R) = Retrievable Filter

PERIPHERAL VASCULAR

SIR vs. Bird's Nest and Gunther Tulip

Potential Complications	Complication/Trackable Event Rates from SIR Guidelines (all filters)[1]	Threshold % from SIR Guidelines (all filters)[2]	Bird's Nest (P) No. of Events (n)	Bird's Nest (P) Complaint Rate[4] (%)	Gunther Tulip (R) No. of Events (n)	Gunther Tulip (R) Complaint Rate[4] (%)
Units Sold	-	-	8,313		120,644	
Cephalad Movement/Migration (2cm+)[3]	0-18%	2%	1	0.012%	23	0.019%
Caudal Movement/Migration (2cm+)[3]			1	0.012%	0	0.000%
Filter Fracture	2-10%	Not Reported	9	0.108%	0	0.000%
Perforation	0-41%	Not Reported	9	0.108%	11	0.009%
Pulmonary Embolism	0.5-6%	5%	1	0.012%	3	0.002%
Caval Thrombosis / Occlusion	2-30%	10%	0	0.000%	2	0.002%
Extravasations of Contrast at time of Cava Gram	Not Reported	Not Reported	Not Reported	-	Not Reported	-
Death (includes all events list above)	0.12%	<1%	1	0.012%	16	0.013%
Tilt	Not Reported	Not Reported	0	0.000%	7	0.006%

[1]Grassi CJ, Swan TL, Cardella JF, et al. Quality Improvement Guidelines for Percutaneous Permanent Inferior Vena Cava Filter Placement for the Prevention of
[2]Suggested threshold for individual practices for purposes of case review.
[3]Migration/Movement includes filter embolization as described in Grassi, above.
[4]Competitor Sales data from IMS Q1 2007

(P) = Permanent Filter
(R) = Retrievable Filter

BARD PERIPHERAL VASCULAR

SIR vs. TrapEase and OptEase

Potential Complications	Complication/Trackable Event Rates from SIR Guidelines (all filters)[1]	Threshold % from SIR Guidelines (all filters)[2]	TrapEase (P) No. of Events (n)	TrapEase (P) Complaint Rate4 (%)	OptEase (R) No. of Events (n)	OptEase (R) Complaint Rate[4] (%)
Units Sold	-	-	252,710		35,266	
Cephalad Movement/Migration (2cm+)[3]	0-18%	2%	40	0.016%	14	0.040%
Caudal Movement/Migration (2cm+)[3]			0	0.000%	1	0.003%
Filter Fracture	2-10%	Not Reported	29	0.011%	11	0.031%
Perforation	0-41%	Not Reported	20	0.008%	0	0.000%
Pulmonary Embolism	0.5-6%	5%	7	0.003%	4	0.011%
Caval Thrombosis / Occlusion	2-30%	10%	65	0.026%	5	0.014%
Extravasations of Contrast at time of Cava Gram	Not Reported	Not Reported	Not Reported	-	Not Reported	-
Death (includes all events list above)	0.12%	<1%	36	0.014%	7	0.020%
Tilt	Not Reported	Not Reported	0	0.000%	1	0.003%

[1]Grassi CJ, Swan TL, Cardella JF, et al. Quality Improvement Guidelines for Percutaneous Permanent Inferior Vena Cava Filter Placement for the Prevention of
[2]Suggested threshold for individual practices for purposes of case review.
[3]Migration/Movement includes filter embolization as described in Grassi, above.
[4]Competitor Sales data from IMS Q1 2007

(P) = Permanent Filter
(R) = Retrievable Filter

PERIPHERAL VASCULAR

Top Filter Complaints per Complication

- **By Failure Mode, Device Ranked by highest defect percentage**

Cephalad Movement/Migration (2cm+)		Caudal Movement/Migration (2cm+)		Filter Fracture		Perforation	
Recovery	0.176%	G2	0.109%	Recovery	0.399%	Bird's Nest	0.108%
OptEase	0.040%	Recovery	0.019%	Bird's Nest	0.108%	Recovery	0.108%
Vena Tech	0.038%	Bird's Nest	0.012%	OptEase	0.031%	G2	0.083%
Greenfield	0.024%	OptEase	0.003%	G2	0.028%	Gunther Tulip	0.009%
Gunther Tulip	0.019%	Vena Tech	0.000%	TrapEase	0.011%	TrapEase	0.008%
G2	0.016%	Greenfield	0.000%	Greenfield	0.004%	Greenfield	0.005%
TrapEase	0.016%	Gunther Tulip	0.000%	Vena Tech	0.001%	Vena Tech	0.000%
Bird's Nest	0.012%	TrapEase	0.000%	Gunther Tulip	0.000%	OptEase	0.000%

Pulmonary Embolism		Caval Thrombosis / Occlusion		Death		Tilt	
Recovery	0.031%	TrapEase	0.026%	Recovery	0.056%	G2	0.109%
Bird's Nest	0.012%	OptEase	0.014%	OptEase	0.020%	Recovery	0.059%
OptEase	0.011%	Recovery	0.012%	TrapEase	0.014%	Gunther Tulip	0.006%
G2	0.010%	G2	0.008%	Gunther Tulip	0.013%	OptEase	0.003%
TrapEase	0.003%	Gunther Tulip	0.002%	Bird's Nest	0.012%	Vena Tech	0.000%
Gunther Tulip	0.002%	Greenfield	0.000%	Vena Tech	0.006%	Greenfield	0.000%
Greenfield	0.002%	Vena Tech	0.000%	G2	0.004%	Bird's Nest	0.000%
Vena Tech	0.001%	Bird's Nest	0.000%	Greenfield	0.002%	TrapEase	0.000%

PERIPHERAL VASCULAR

EXHIBIT K
(Filed Under Seal)

EXHIBIT L
(Filed Under Seal)

EXHIBIT M
(Filed Under Seal)

EXHIBIT N
(Filed Under Seal)

EXHIBIT O

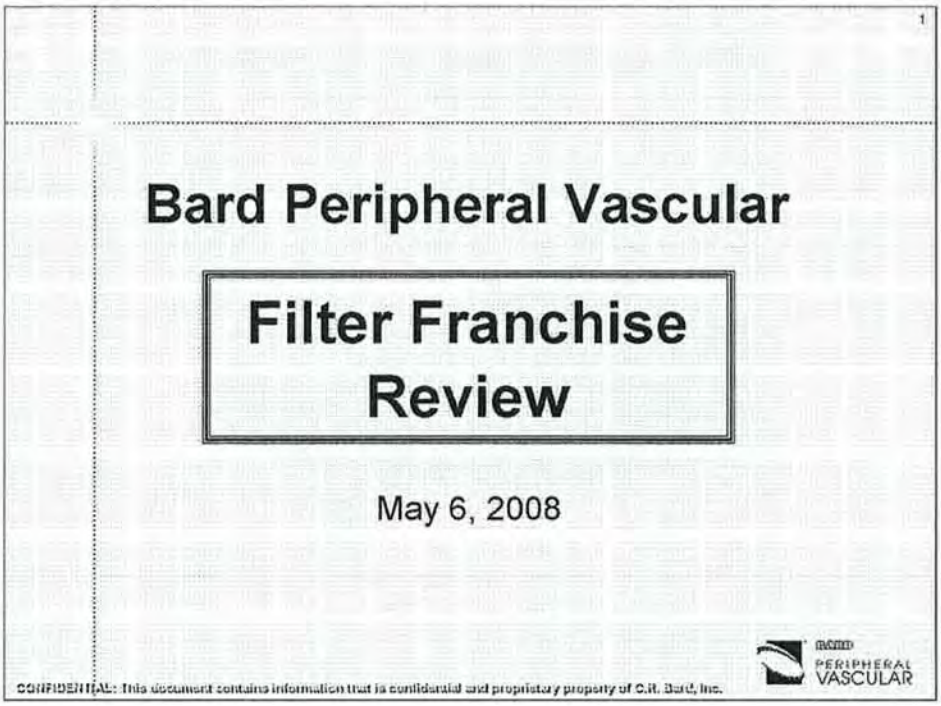
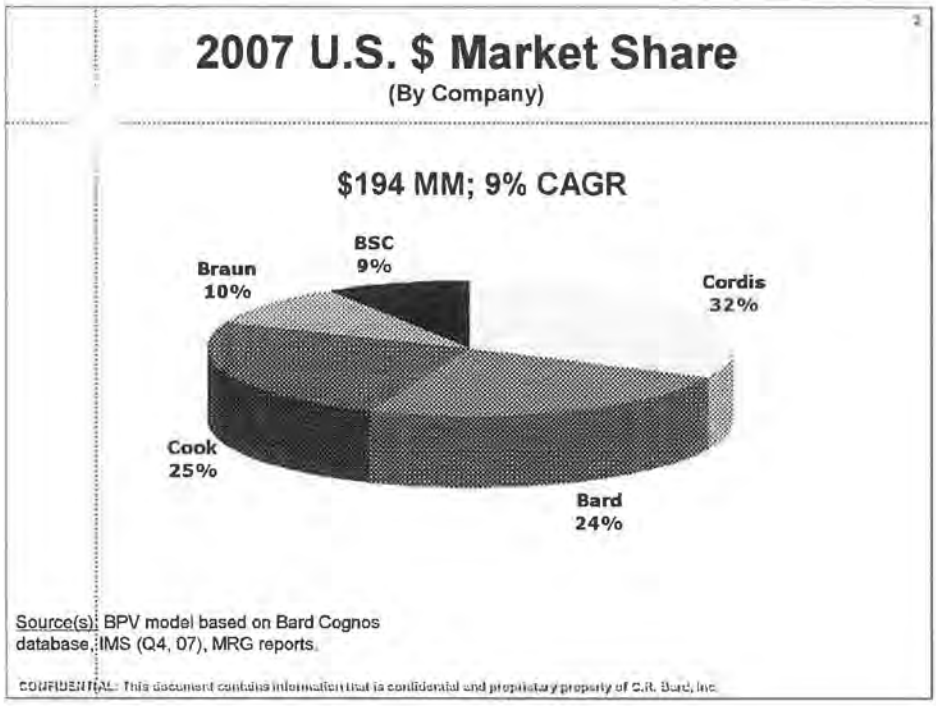


EXHIBIT NO. 14
TESMER
6/12/13


2007 U.S. $ Market Share
(By Company)
$194 MM; 9% CAGR
BSC
9%
Braun
10%
Cordis
32%
Cook
25%
Bard
24%
Source(s): BPV model based on Bard Cognos database, IMS (Q4, 07), MRG reports.
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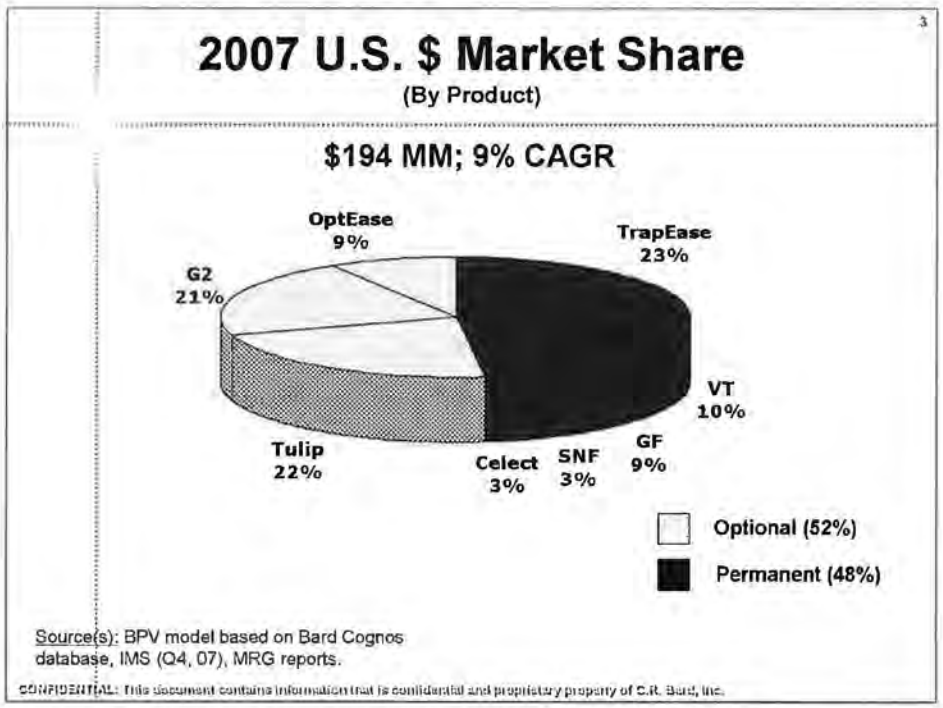

- Celect estimated to be about 3% of the Cook number
- Does not much news, seems to be more of a LMR. Not even showing up on our internal tracking info from HSI
- OptEase has been at 9% for a while. TrapEase users like idea of retrievable but the filter has not attained broader market acceptance, indwell time is probably one of the bigger reasons

•No permanent filters being developed, everything is being designed to be optional

•Field big source of info, Corporate, VP of Reimbursement Dave Parr, coded as foreign body retrieval 37203

•ASC = Ambulatory Service Center

•New entrants lack of good filter data, filters perceived as last resort, medical community not know answer, anticoag has its own problems


5
Key Market Trends (cont.)
But the Optional Market Growth is being hampered:
– Recent clinical data focuses on complications associated with optional filters
– There is a perceived risk / benefit tradeoff for marginally indicated patients with the attitude there is no "benign" filter
– Insufficient implant referral base awareness of possible benefits of optional filters
– Lack of education opportunities to implant & retrieve
– Poor tracking in hospitals for follow up retrieval (tracking software value)
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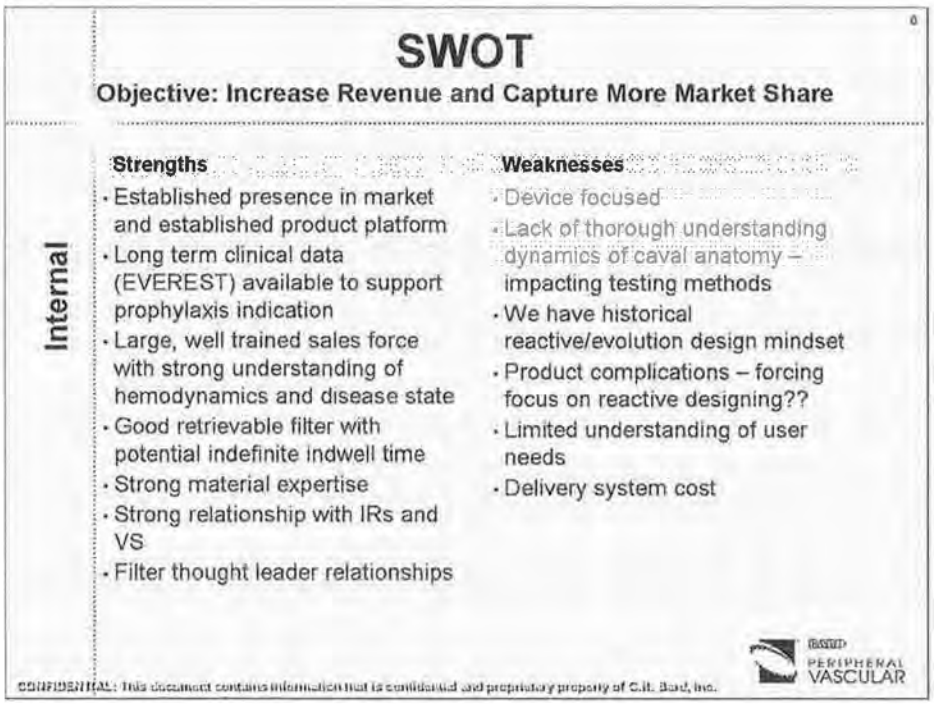
SWOT
Objective: Increase Revenue and Capture More Market Share
Internal
Strengths
• Established presence in market and established product platform
• Long term clinical data (EVEREST) available to support prophylaxis indication
• Large, well trained sales force with strong understanding of hemodynamics and disease state
• Good retrievable filter with potential indefinite indwell time
• Strong material expertise
• Strong relationship with IRs and VS
• Filter thought leader relationships
Weaknesses
• Device focused
• Lack of thorough understanding dynamics of caval anatomy – impacting testing methods
• We have historical reactive/evolution design mindset
• Product complications – forcing focus on reactive designing??
• Limited understanding of user needs
• Delivery system cost
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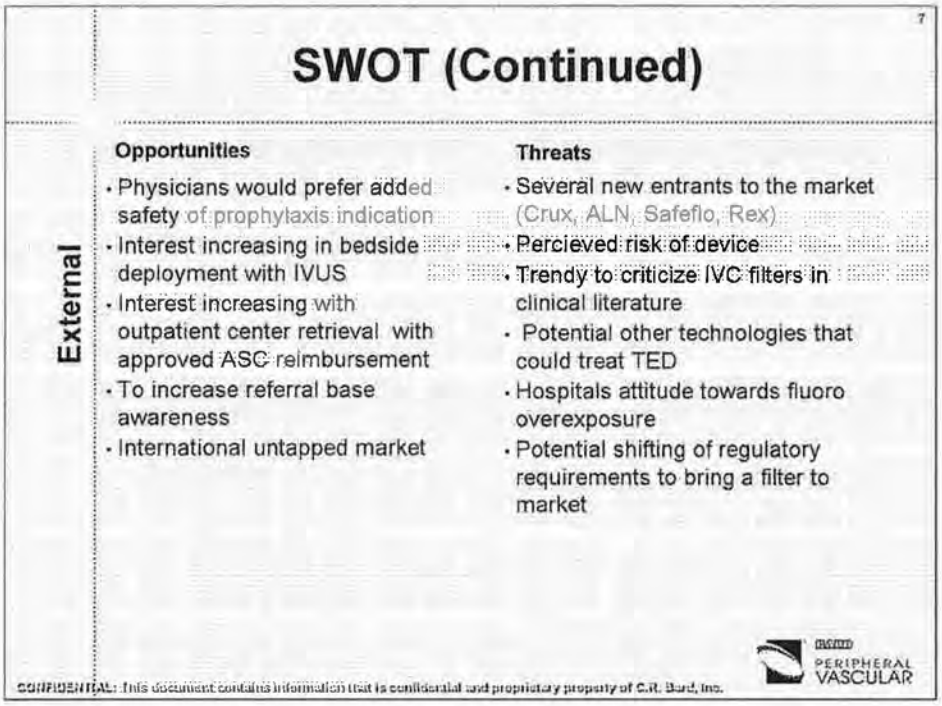
7
SWOT (Continued)
External
Opportunities
• Physicians would prefer added safety of prophylaxis indication
• Interest increasing in bedside deployment with IVUS
• Interest increasing with outpatient center retrieval with approved ASC reimbursement
• To increase referral base awareness
• International untapped market
Threats
• Several new entrants to the market (Crux, ALN, Safeflo, Rex)
• Percieved risk of device
• Trendy to criticize IVC filters in clinical literature
• Potential other technologies that could treat TED
• Hospitals attitude towards fluoro overexposure
• Potential shifting of regulatory requirements to bring a filter to market
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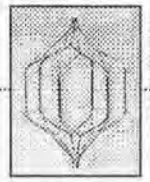
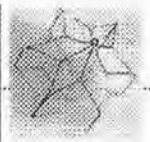
PERIPHERAL VASCULAR

Cordis



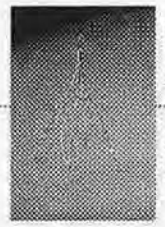


- Market Leader
  - 37% Market Share ($); 36% (units)
- Product Offering
  - **TrapEase** (Permanent)
  - **OptEase** (Optional)

Strengths	Weaknesses
Ease of use Bi-directional filter Low Profile Low price Retrieval indication (Optease)	Inverted conical design Perceived caval thrombosis issues Lack of support from filter thought leaders Short window of retrievability

BARD PERIPHERAL VASCULAR

Cook



- Strong Competitor
  - 16% Market Share ($); 22% (units)
- Product Offering
  - **Celect (Optional)** – *retrievable indication with long window of retrievability, but minimum caval diameter limitations*
  - **Günther Tulip (Optional)** - *reputation for low complications, but limited window of retrievability*
  - **Bird's Nest (Permanent)** – *can be placed in larger cavas*

Strengths	Weaknesses
• Longevity • Positive market momentum • Low price alternatives	• Both optional filters prone to Tilting • Weak sales force with larger territories

BARD PERIPHERAL VASCULAR

Other Permanent (BBraun & Boston)

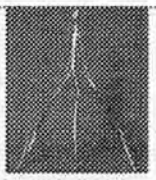
- BBraun
  - 13% Market Share ($); 13% (units)
  - **Vena Tech LP and LGM** (Permanent) – *bidirectional filters, easy to use with low prices and perceived low complication rates, but no dual level filtration and weak sales force*

- Boston Scientific
  - 9% Market Share ($); 10% (units)
  - **Greenfield SS and Ti** (Permanent) – *clinic history and strong sales force supporting ease of use and low price, but no dual level filtration and prone to tilt; larger profile as well with single femoral side delivery*

11

Other New Entrants

- Rex Medical (Option Filter)
  - Low profile and optional, but no real new technology advancements
- ALN (ALN Filter)
  - Optional filter marketed by distributor in U.S.; tilting risks
- Rafael Medical (SafeFlo Filter)
  - Optional filter
- BBraun (Convertible Filter)



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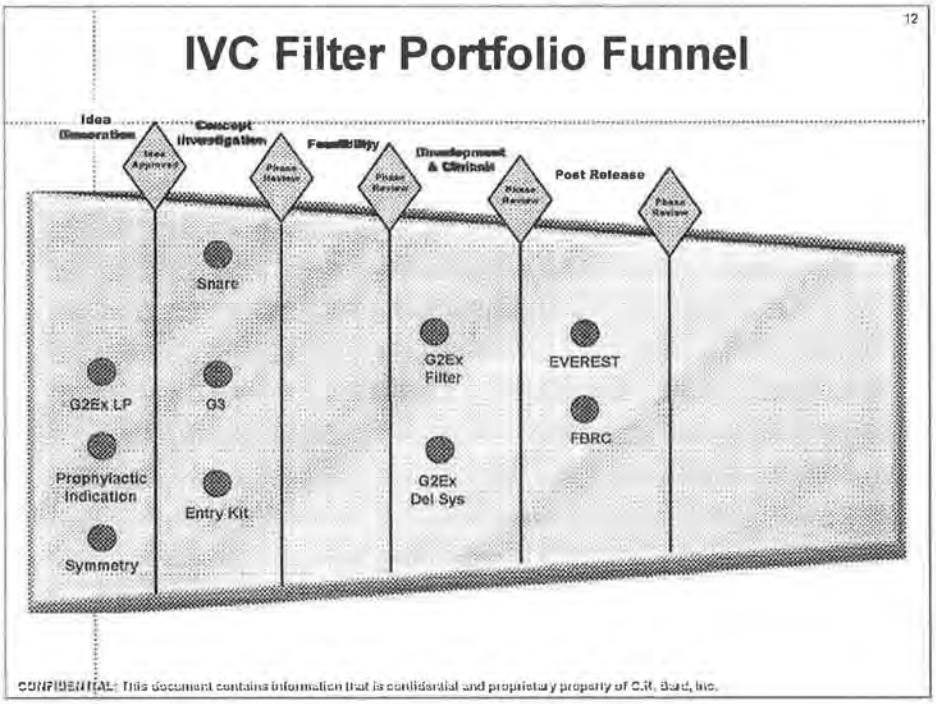
12
IVC Filter Portfolio Funnel
Idea Generation
Idea Approved
Concept Investigation
Phase Review
Feasibility
Phase Review
Development & Clinical
Phase Review
Post Release
Phase Review
Snare
G2Ex LP
G3
G2Ex Filter
EVEREST
FBRC
Prophylactic Indication
Entry Kit
G2Ex Del Sys
Symmetry
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13
U.S. Filter Sales History
Sales ($ Million)
50
45
40
35
30
25
20
15
10
5
0
$12.1
$16.1
$30.8
$31.9
$36.3
$45.9
$6.4
$39.3
$28.9
'02
'03
'04
'05
'06
'07
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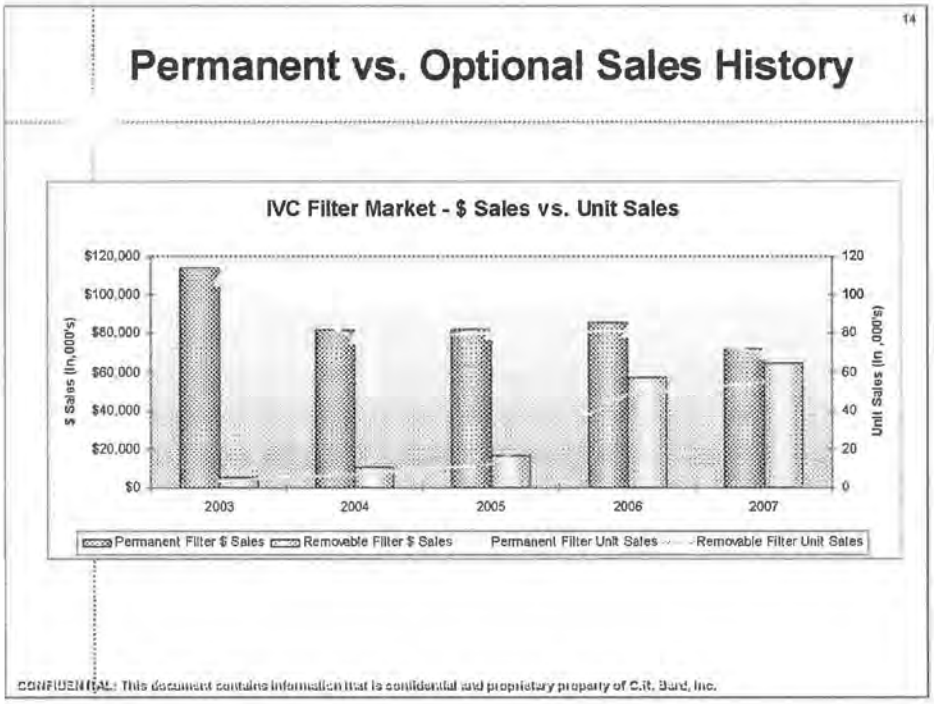
14
Permanent vs. Optional Sales History
IVC Filter Market - $ Sales vs. Unit Sales
$120,000
$100,000
$80,000
$60,000
$40,000
$20,000
$0
$ Sales (In,000's)
120
100
80
60
40
20
0
Unit Sales (In ,000's)
2003
2004
2005
2006
2007
Permanent Filter $ Sales
Removable Filter $ Sales
Permanent Filter Unit Sales
Removable Filter Unit Sales
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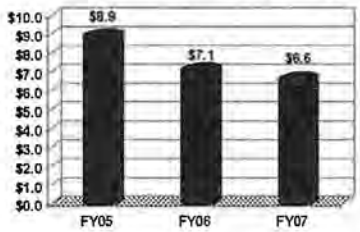
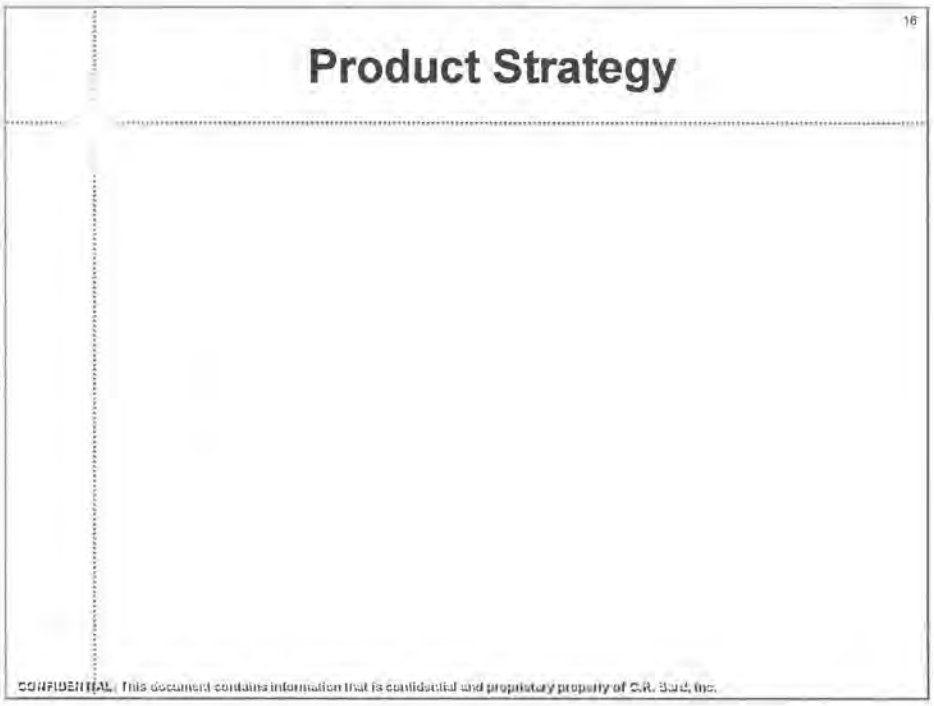
15

Is SNF Relevant?

- Cost Conscious Customers
  - VA Hospitals
  - Community Hospitals
  - Physician Owned Clinics
- Clinical Need
  - Certain types of patients
- With Everest BPV truly has Permanent and Optional Filters

SNF Revenue (MM)

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Product Strategy
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Product Strategy
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18
Filter Franchise Improvements
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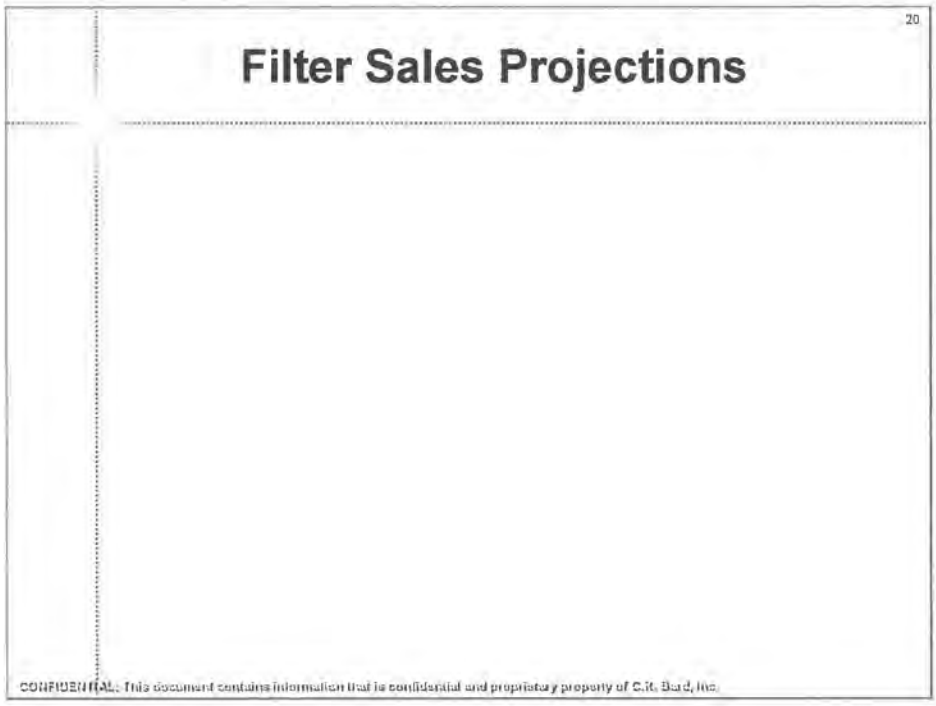
ASP Comparison

Optional	
G2	$1,270
OptEase	$1,278
Gunther-Tulip	$956
Celect	N/A
Non-weighted average	$1,183

Permanent	
TrapEase	$1,135
Bird's Nest	$1,071
VenaTech	$1,061
Greenfield	$940
Simon Nitinol	$902
Non-weighted average	$1,022


20
Filter Sales Projections
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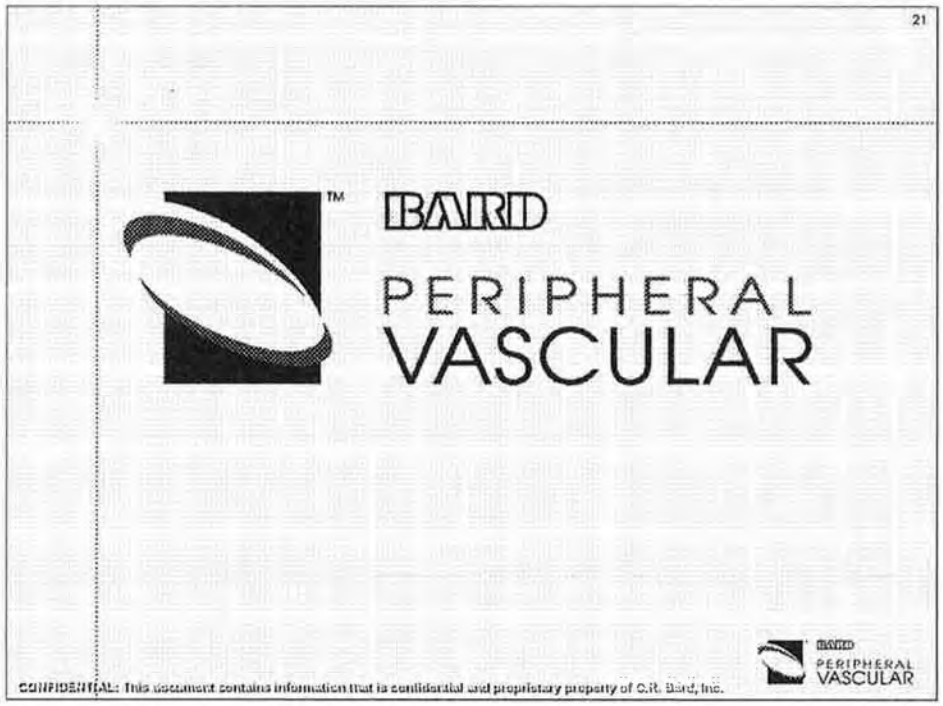
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BARD
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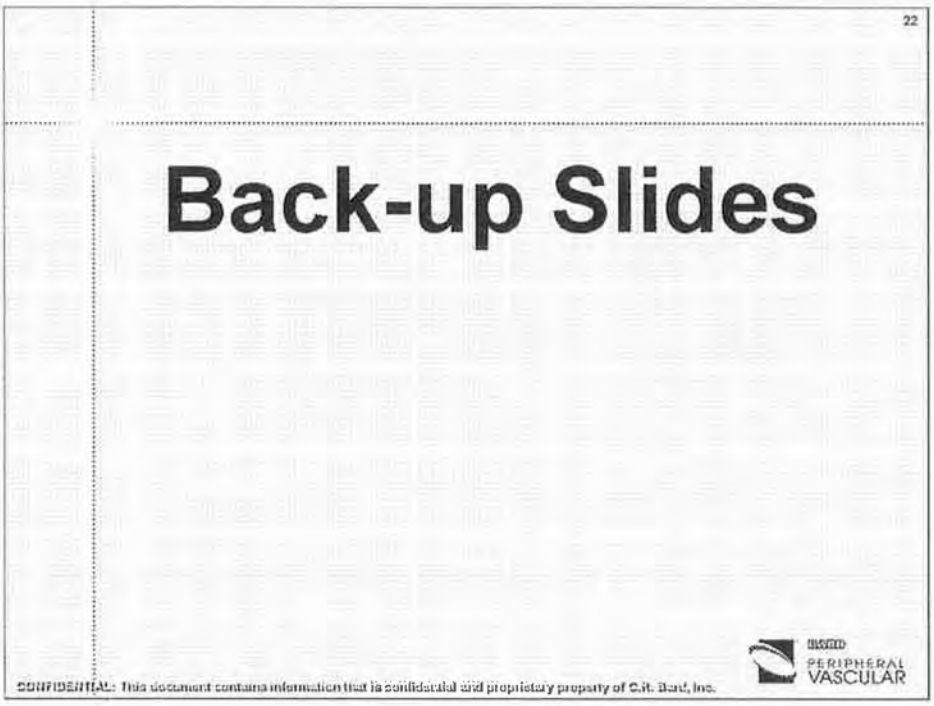
VASCULAR


22
Back-up Slides
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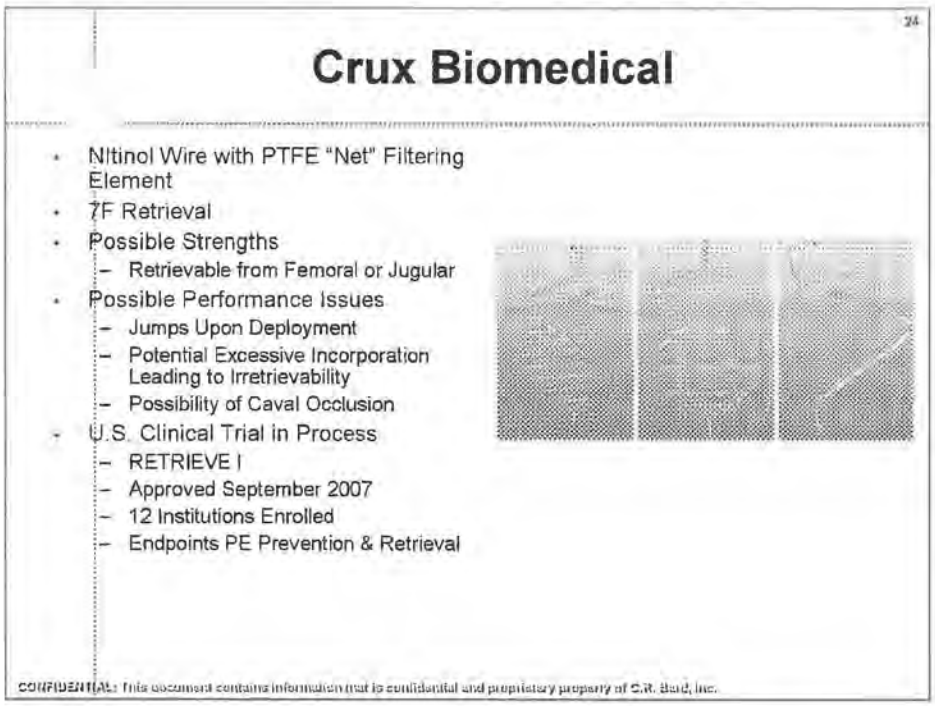
Snares

U.S. Standard Snare Market ($30M)

G2 EXPRESS®
VENA CAVA FILTER

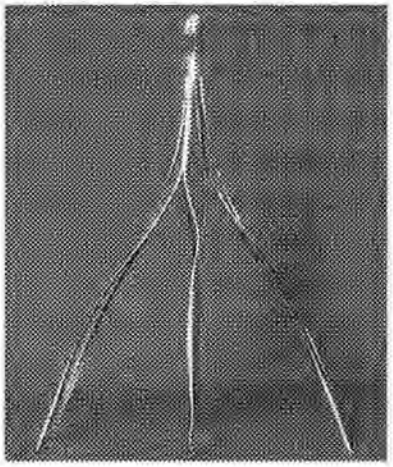


- Heard of downward jump
- Excessive incorporation issues
- Probably be occluder
- Trial is in progress in the US

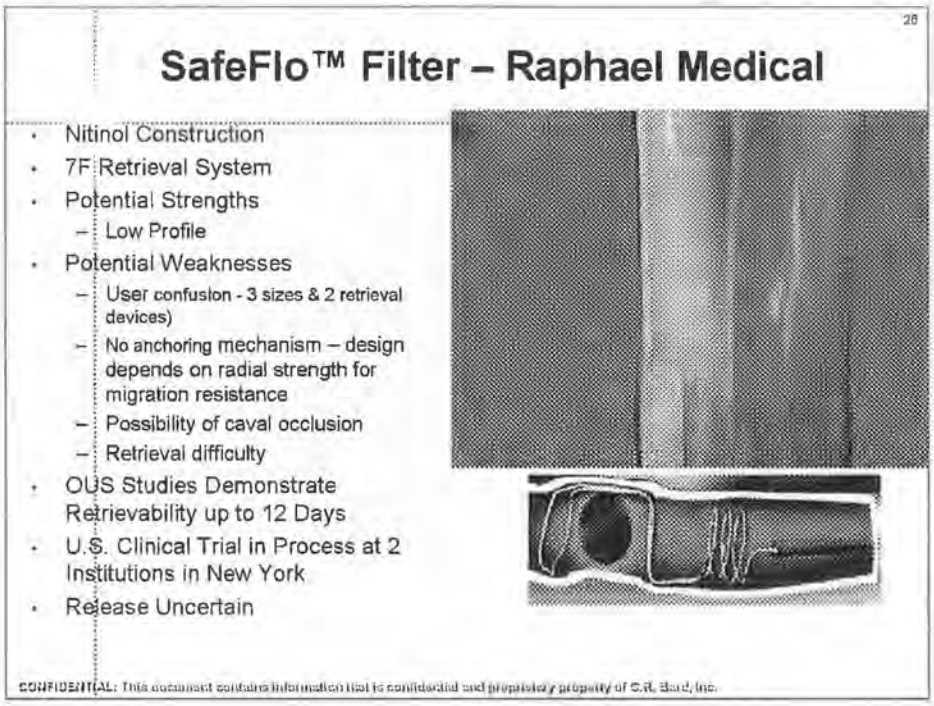
25

Option* LT (Rex Medical)

- Laser-Cut Nitinol Tube
- Single Level Conical Design
- Angiotech Signed Licensing Deal March 13
- Potential Strengths
  - 5F Profile
- Potential Weaknesses
  - Tilting an Issue
  - Possibility of Guidewire Entrapment
- Performance Similar to that of Gunther-Tulip
- 14 – 107 Day Retrievals OUS
- U.S. Clinical Trial in Process
  - Reports of Tilting
  - Retrieval Issues
  - Reports of 14 - 107 Day Indwell
  - Enrollment Complete Q2 2008
- U.S. Release Late 2008



- Something of a threat, low profile
- Gregg Pichler less than 50% success rate 3 weeks
- Made like TrapEase
- Tilting problem
- Venbrooks speaker
- US AIM/VEITH, 20 days mean, 6-175 days, paper at SIR
- Abbott, BSCI, Terumo
- Hooks twist, torquing cava



•3 sizes, wrong size chosen, downside of 3 different sized filters, too small embolus, too large perf,

•No fixation just radial force

•Flat filter with wires

•What is issue with flat filter element??? Occlusion.

•Eggbeater retrieval device… Raphael Medical characterize it like a eggbeater

•Heard FDA had issues with trial

List Prices

27

OptEase	$1,695 / $1,795
Celect	$1,395 / $1,300
G2	$1,395
SS Greenfield	$1,199
TrapEase	$1,195 / $1,295
Gunther-Tulip	$1,125
Vena Tech LP	$1,085
Ti Greenfield	$1,099
Bird's Nest	$1,049
Simon Nitinol	$1,035
Vena Tech	$895 / $995


28
EVEREST Commercialization
FDA concurrence Jan 15
Field communication
– IFU available 1/18
– Informational Webcast for Sales - Jan 21
Abstract presentation at SIR - Mar 15
EVEREST
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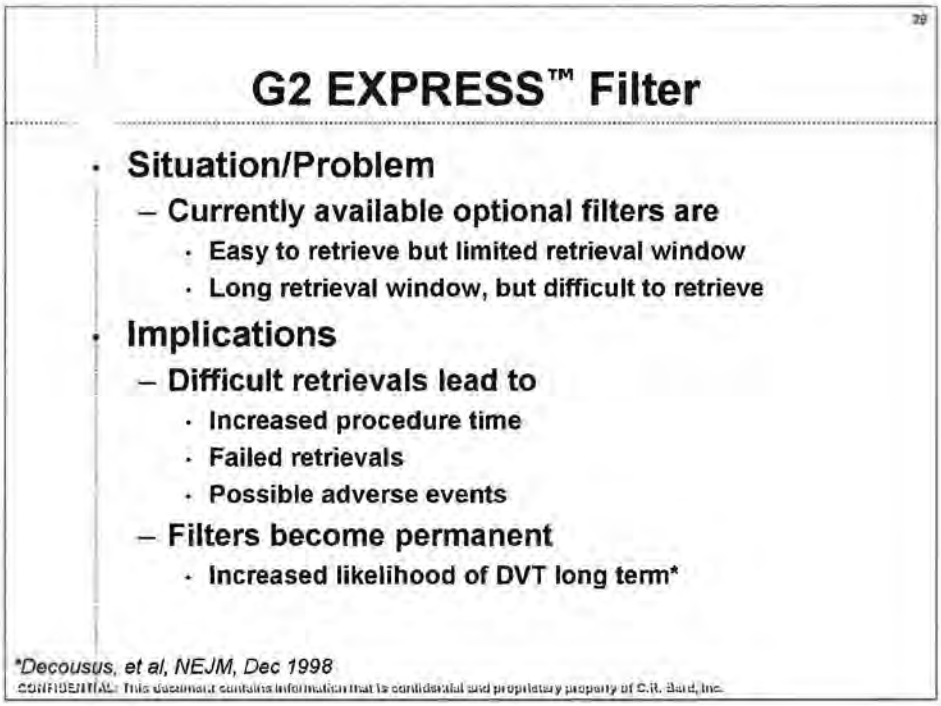
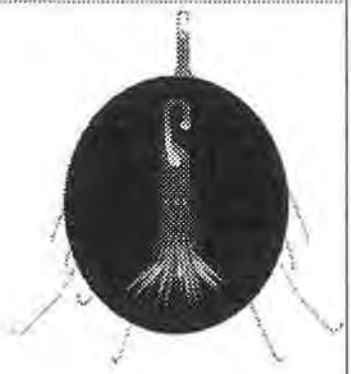


Speak to leveraging new indication to better meet customer needs

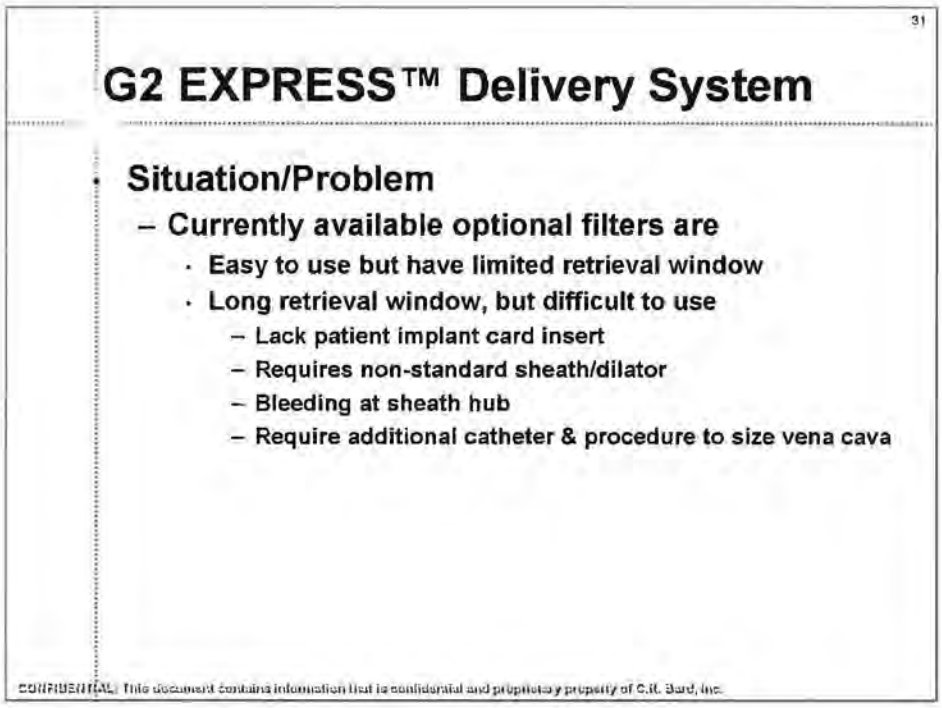
30

G2 EXPRESS™ Filter

- **Solution**
  - Add snare tip to the G2® Filter
- **Status/Action Plan**
  - DV & V Phase
  - Submit Special 510(K) - March
  - Introduce at SIR



G2 EXPRESS


31
G2 EXPRESS™ Delivery System
Situation/Problem
– Currently available optional filters are
· Easy to use but have limited retrieval window
· Long retrieval window, but difficult to use
– Lack patient implant card insert
– Requires non-standard sheath/dilator
– Bleeding at sheath hub
– Require additional catheter & procedure to size vena cava
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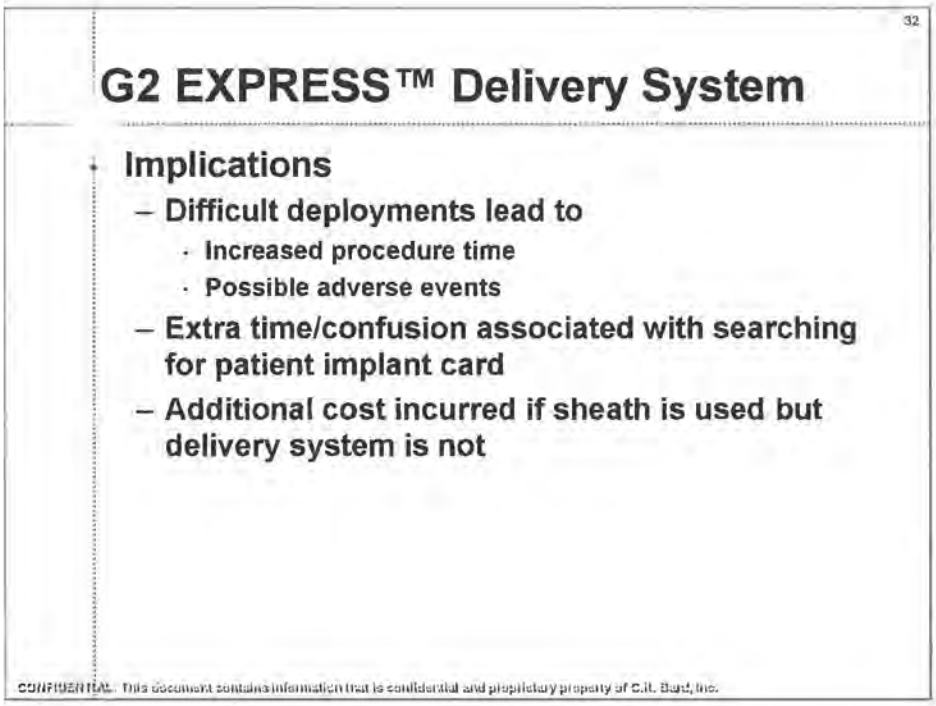
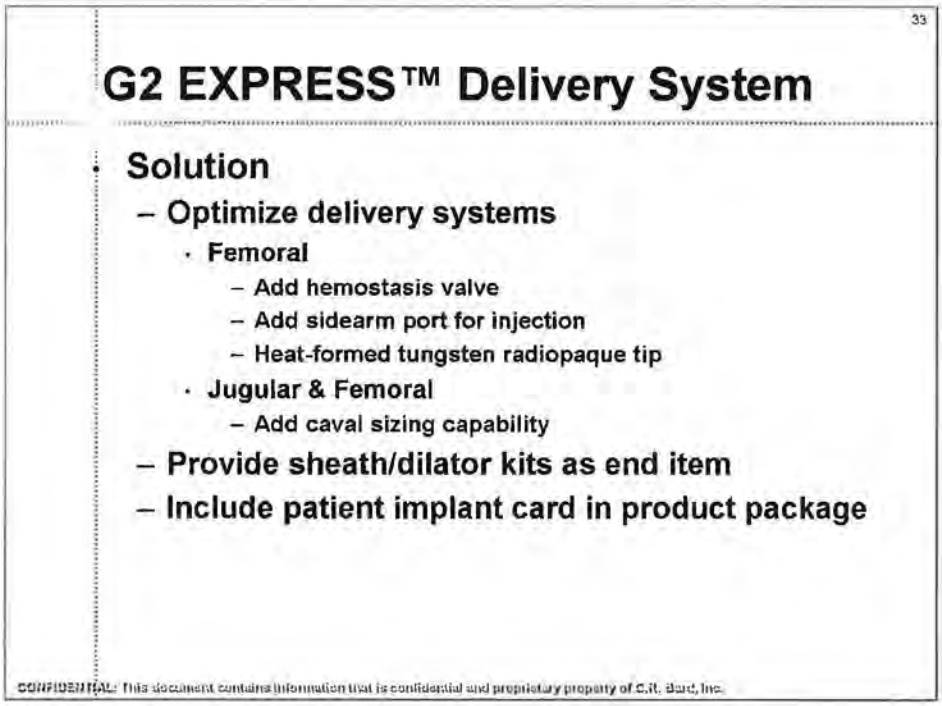


32

G2 EXPRESS™ Delivery System

- Implications
  - Difficult deployments lead to
    - Increased procedure time
    - Possible adverse events
  - Extra time/confusion associated with searching for patient implant card
  - Additional cost incurred if sheath is used but delivery system is not


33
G2 EXPRESS™ Delivery System
Solution
– Optimize delivery systems
• Femoral
– Add hemostasis valve
– Add sidearm port for injection
– Heat-formed tungsten radiopaque tip
• Jugular & Femoral
– Add caval sizing capability
– Provide sheath/dilator kits as end item
– Include patient implant card in product package
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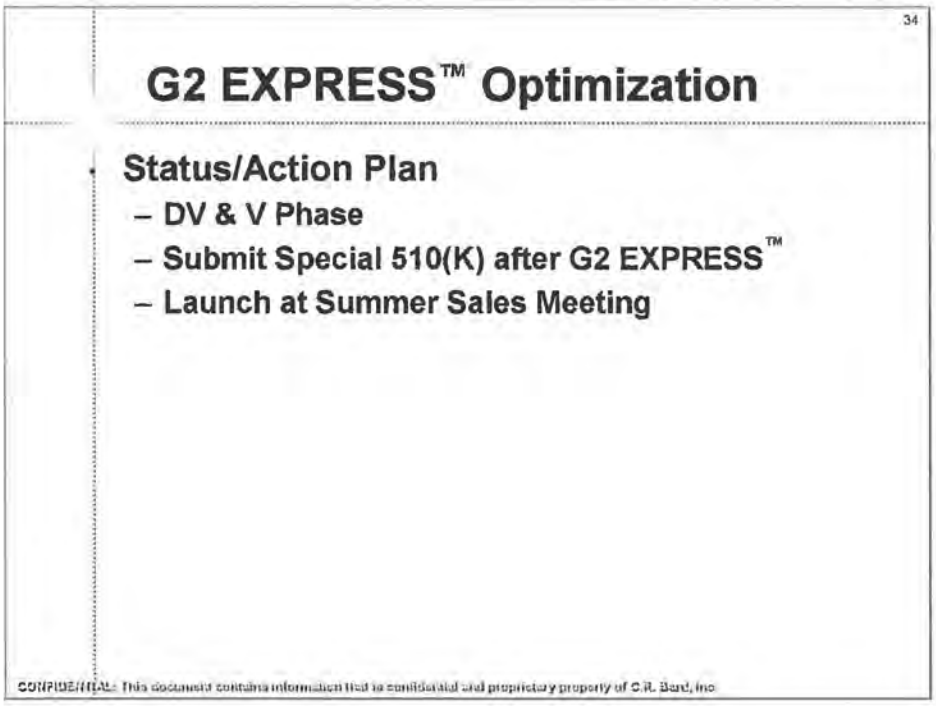
34
G2 EXPRESS™ Optimization
Status/Action Plan
– DV & V Phase
– Submit Special 510(K) after G2 EXPRESS™
– Launch at Summer Sales Meeting
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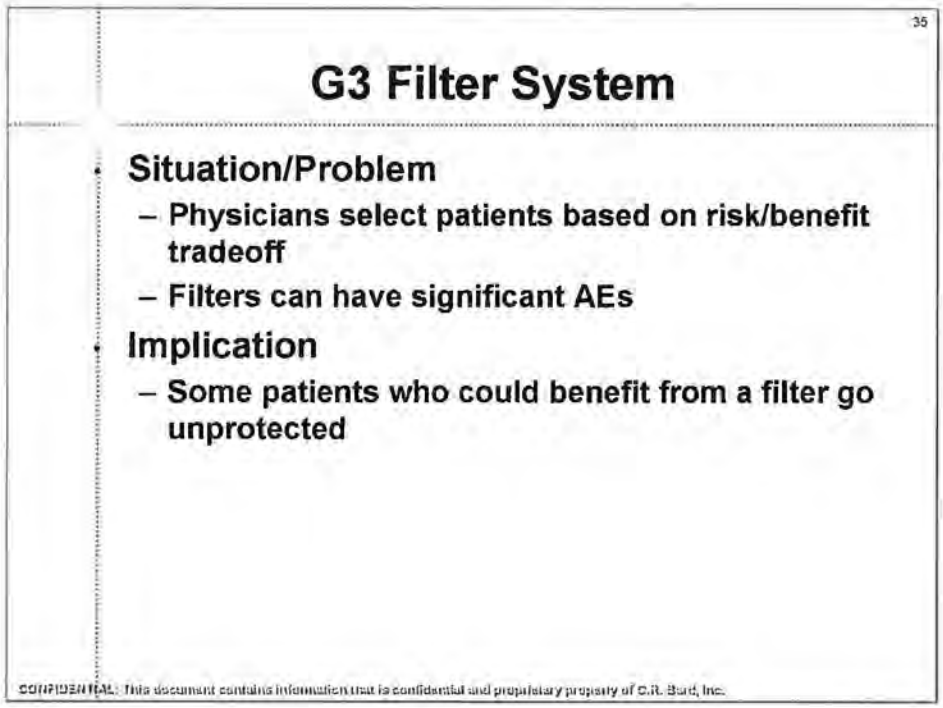
35
G3 Filter System
Situation/Problem
– Physicians select patients based on risk/benefit tradeoff
– Filters can have significant AEs
Implication
– Some patients who could benefit from a filter go unprotected
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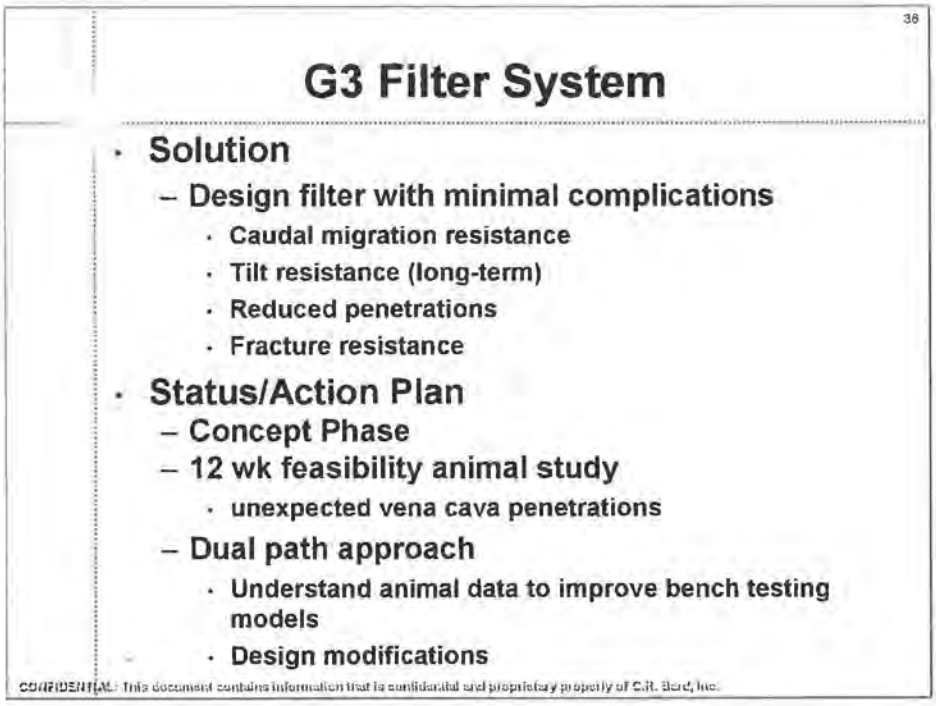
36
G3 Filter System
Solution
Design filter with minimal complications
Caudal migration resistance
Tilt resistance (long-term)
Reduced penetrations
Fracture resistance
Status/Action Plan
Concept Phase
12 wk feasibility animal study
unexpected vena cava penetrations
Dual path approach
Understand animal data to improve bench testing models
Design modifications
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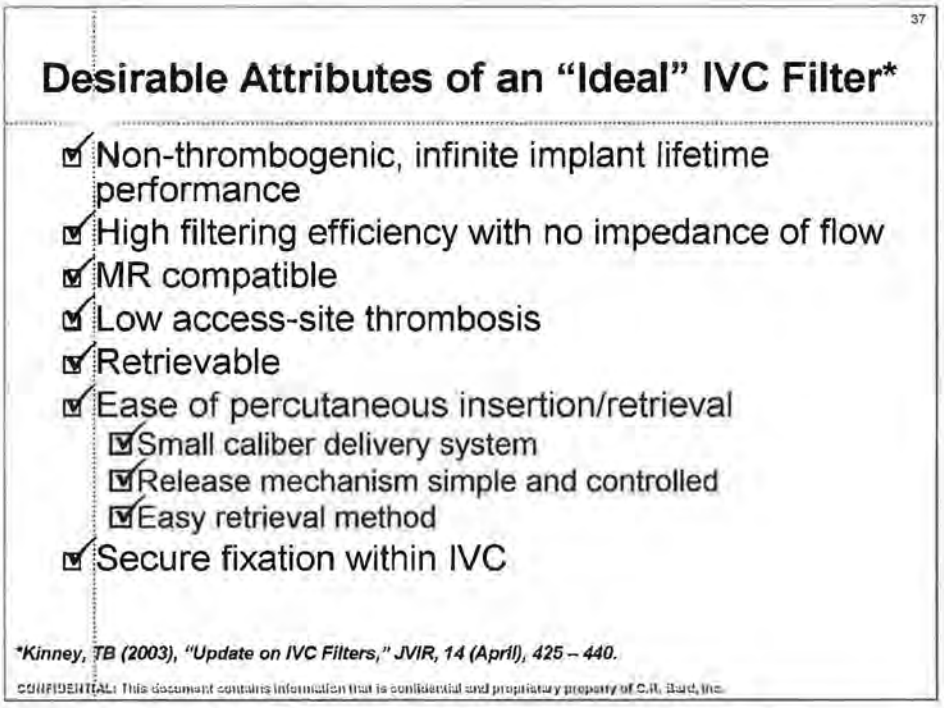
37
Desirable Attributes of an "Ideal" IVC Filter*
Non-thrombogenic, infinite implant lifetime performance
High filtering efficiency with no impedance of flow
MR compatible
Low access-site thrombosis
Retrievable
Ease of percutaneous insertion/retrieval
Small caliber delivery system
Release mechanism simple and controlled
Easy retrieval method
Secure fixation within IVC
*Kinney, TB (2003), "Update on IVC Filters," JVIR, 14 (April), 425 – 440.
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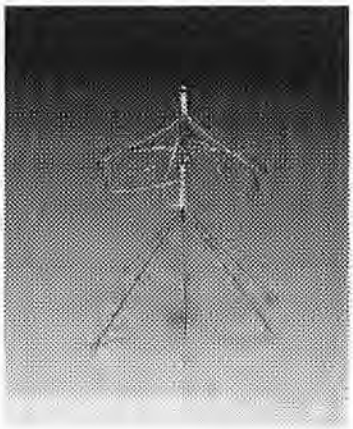
Filter NPD Update

Program Update	September Plan	March Plan
EVEREST	Q1/Q2 '08	Jan '08
G2 Express	Q2 '08	Q2 '08
G2 Express Filter	Q2 '08	4/15/08
G2EX Delivery System	Q2 '08	Q2 '08
G3 Filter	H1 2010	TBD

39

Simon Nitinol Filter



- First Nitinol Vascular Implant
- First Bi-Level Filter
- First Low-Profile 7F ID Delivery System
  - Indicated for R/L Femoral, Jugular, Subclavian and Antecubital Access
- Released in 1990 with Over 17 Years of Proven Efficacy
- Implanted in over 150,000 patients

EXHIBIT P
(Filed Under Seal)

EXHIBIT Q
(Filed Under Seal)